

# Summary of typical bone-graft substitutes that are commercially available - 2010

| Company               | Commercially available product | Composition  | Commercially available forms  | Claimed mechanisms of action   | Burdens of proof  | FDA status  |
|-----------------------|--------------------------------|--|---|--|---|---|
| AlloSource            | AlloFuse™                      | Heat sensitive copolymer with DBM                              | Injectable gel and putty  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> <li>Cell culture</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul>              |
| Biomet Osteobiologics | BonePlast®                     | Calcium sulfate with or without HA/CC composite granules       | Various volumes of powder and setting solution                          | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
|                       | BonePlast® Quick Set           | Calcium sulfate  | Quick setting paste   | <ul style="list-style-type: none"> <li>Osteoconductive</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
|                       | InterGro®                      | DBM in a lecithin carrier                                      | Paste, putty and mix with HA/CC composite granules                      | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested for osteoinduction</li> </ul>                                       | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul>              |
|                       | ProOsteon® 500R                | Coralline-derived HA/CC composite                              | Granular or block   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>   | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
| DePuy Spine           | CONDUIT® TCP Granules          | 100% β-TCP   | Granules  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
|                       | HEALOS® Bone Graft Replacement | Mineralized collagen matrix                                    | Variety of strip sizes  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Creeping substitution</li> <li>Osteoinduction</li> <li>Osteogenesis when mixed with bone marrow aspirate</li> </ul>                                    | <ul style="list-style-type: none"> <li>Peer-reviewed, published human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>                                    | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler: Must be used with autogenous bone marrow</li> </ul> |
| Exactech              | Optecure®                      | DBM suspended in a hydrogel carrier                            | Dry mix kit delivered with buffered saline                              | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> <li>Osteogenesis when mixed with autogenous bone graft</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul>              |
|                       | Optecure® + CCC                | DBM and CCC suspended in a hydrogel carrier                    | Dry mix kit delivered with buffered saline                              | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> <li>Osteogenesis when mixed with autogenous bone graft</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul>              |
|                       | Optefil®                       | DBM suspended in gelatin carrier                               | Injectable bone paste-dry powder ready to be hydrated                   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> <li>Osteogenesis when mixed with autogenous bone graft</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
|                       | Opteform®                      | DBM and cortical cancellous chips suspended in gelatin carrier | Formable putty or dry powder ready to be hydrated                       | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> <li>Osteogenesis when mixed with autogenous bone graft</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
|                       | OpteMx™                        | HA/TCP biphasic combination                                    | Granules, sticks, rounded wedges, wedges and cylinders in several sizes | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Compressive strength of 400psi</li> <li>Osteogenesis and limited osteoinduction when mixed with bone marrow aspirate</li> </ul> | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>   | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |

β-TCP - β-tricalcium phosphate  
CBM - Cancellous bone matrix

CCC - Cortical cancellous chips  
DBM - Demineralized bone matrix

HA/CC - Hydroxyapatite/calcium carbonate

PMA – Pre-Market Application; HDE – Humanitarian Device Exemption

| Company  | Commercially available product | Composition   | Commercially available forms  | Claimed mechanisms of action   | Burdens of proof   | FDA status   |
|--|--------------------------------|---|---|--|--|--|
| Integra Orthobiologics/<br>(IsoTis Orthobiologics) | Accell Connexus®               | DBM, Accell Bone Matrix, Reverse Phase Medium                     | Injectable putty  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every DBM lot tested for osteoinduction</li> </ul> | 510(k) cleared<br>Extremities, Pelvis<br>• Bone Void Filler<br>Extremities, Pelvis, Spine<br>• Bone Graft Extender |
|  | Accell Evo3™                   | DBM, Accell Bone Matrix, Reverse Phase Medium                     | Injectable putty  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> <li>Every DBM lot tested for osteoinduction</li> </ul>  | 510(k) cleared<br>Extremities, Pelvis<br>• Bone Void Filler<br>Extremities, Pelvis, Spine<br>• Bone Graft Extender |
|  | Accell TBM®                    | DBM, Accell Bone Matrix   | Various sized strips  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every DBM lot tested for osteoinduction</li> </ul> | 510(k) cleared<br>Extremities, Pelvis<br>• Bone Void Filler<br>Extremities, Pelvis, Spine<br>• Bone Graft Extender |
|  | DynaGraft II                   | DBM, Reverse Phase Medium   | Injectable putty  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every DBM lot tested for osteoinduction</li> </ul> | 510(k) cleared   |
|  | OrthoBlast II                  | DBM, cancellous bone, Reverse Phase Medium                        | Injectable putty  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every DBM lot tested for osteoinduction</li> </ul> | 510(k) cleared<br>Extremities, Pelvis<br>• Bone Void Filler<br>Extremities, Pelvis, Spine<br>• Bone Graft Extender |
|  | Integra Mozaik™                | 80% highly purified β-TCP/<br>20% highly purified Type-1 collagen | Strip and putty   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared<br>Extremities, Pelvis, Spine<br>• Bone Void Filler   |
| Life Net Health                                    | IC Graft Chamber®              | DBM particles and cancellous chips                                | Lyophilized and packaged in various sizes within a delivery chamber | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> <li>Designed to be used with blood, PRP or bone marrow to enhance DBM activity</li> </ul> | <ul style="list-style-type: none"> <li>Animal studies</li> <li>Case reports</li> </ul>   | • Regulated under CFR 1270 and 1271 as a human tissue and 510(k) cleared   |
|  | Optium DBM®                    | DBM combined with glycerol carrier                                | Formable putty (bone fibers) and injectable gel (bone particles)    | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared<br>• Bone Void Filler   |
| Medtronic Spinal & Biologics                       | INFUSE® Bone Graft             | rhBMP-2 protein on an absorbable collagen sponge                  | Multiple kit sizes  | <ul style="list-style-type: none"> <li>Bioresorbable carrier</li> <li>Osteoinduction</li> <li>Chemotaxis of stem cells; indirect osteogenesis</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies (Level I and Level III data)</li> <li>Case reports</li> <li>Animal studies</li> </ul>                     | • PMA approved for fusion with spinal cage<br>• PMA approved for open tibia fractures with IM nail                 |
|  | MasterGraft® Granules          | Biphasic calcium phosphate (15% HA / 85% β-TCP)                   | Granules  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> <li>Case reports</li> </ul>   | 510(k) cleared<br>• Bone Void Filler   |
|  | MasterGraft® Matrix            | Biphasic calcium phosphate and collagen                           | Compression resistant block   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> <li>Case reports</li> </ul>   | 510(k) cleared<br>• Bone Void Filler:<br>Must be used with autogenous bone marrow                                  |

β-TCP - β-tricalcium phosphate  
CBM - Cancellous bone matrix

CCC - Cortical cancellous chips  
DBM - Demineralized bone matrix

HA/CC - Hydroxyapatite/calcium carbonate

PMA – Pre-Market Application; HDE – Humanitarian Device Exemption

| Company                      | Commercially available product | Composition   | Commercially available forms                 | Claimed mechanisms of action   | Burdens of proof  | FDA status  |
|------------------------------|--------------------------------|---|--|--|---|---|
| Medtronic Spinal & Biologics | MasterGraft® Putty             | Biphasic calcium phosphate and collagen   | Moldable putty                               | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Extender: Must be used with autograft</li> <li>Bone Void Filler: Must be used with autogenous bone marrow and/or autograft and/or sterile water</li> </ul> |
|                              | MasterGraft® Strip             | Biphasic calcium phosphate (15% HA and 85% $\beta$ -TCP) and collagen                                     | Compression resistant strip                  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler: Must be used with autogenous bone marrow</li> </ul>   |
|                              | Osteofil® DBM                  | DBM in porcine gelatin  | Injectable paste and moldable strips         | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> <li>Case reports</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
|                              | Progenix™ Plus                 | DBM in Type-1 bovine collagen and sodium alginate   | Putty with demineralized cortical bone chips | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> <li>Case reports</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul>   |
|                              | Progenix™ Putty                | DBM in Type-1 bovine collagen and sodium alginate   | Ready to use injectable putty                | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> <li>Case reports</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Extremities, Pelvis</li> <li>Bone Graft Substitute</li> <li>Bone Void Filler</li> <li>Spine</li> <li>Bone Graft Extender: Must be used with autograft bone</li> </ul> |
| MTF/Orthofix                 | Trinity Evolution™             | Viable Cellular Bone Matrix   | Multiple volumes available                   | <ul style="list-style-type: none"> <li>Osteogenesis</li> <li>Osteoinduction</li> <li>Osteoconduction</li> </ul>  | <ul style="list-style-type: none"> <li>Animal Studies</li> <li>Case Reports</li> </ul>  | <ul style="list-style-type: none"> <li>Regulated under CFR 1270 and 1271 as a human tissue.</li> </ul>  |
| MTF/Synthes                  | DBX®                           | DBM in sodium hyaluronate carrier   | Paste, putty mix and strip                   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>                             | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul>  |
| NovaBone/MTF                 | NovaBone®                      | Bioactive silicate  | Particulate, putty and morsels               | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteostimulation</li> </ul>   | <ul style="list-style-type: none"> <li>Published human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>                   | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
| Orthovita                    | Vitoss®                        | 100% $\beta$ -TCP and 80% $\beta$ -TCP/20% collagen and 70% $\beta$ -TCP/20% collagen/10% bioactive glass | Putty, strip, flow, morsels and shapes       | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Bioactive/osteostimulation</li> <li>Osteogenesis and osteoinduction when mixed with bone marrow aspirate</li> </ul> | <ul style="list-style-type: none"> <li>Published human studies (Level I and III)</li> <li>Case reports</li> <li>Animal studies</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |

$\beta$ -TCP -  $\beta$ -tricalcium phosphate  
CBM - Cancellous bone matrix

CCC - Cortical cancellous chips  
DBM - Demineralized bone matrix

HA/CC - Hydroxyapatite/calcium carbonate

PMA – Pre-Market Application; HDE – Humanitarian Device Exemption

| Company   | Commercially available product   | Composition                                  | Commercially available forms          | Claimed mechanisms of action   | Burdens of proof   | FDA status  |
|-----------|----------------------------------|--|---------------------------------------|--|--|---|
| Osteotech | GRAFTON® A-Flex®                 | DBM fiber technology                         | Round flexible sheet                  | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case Reports</li> <li>Animal Studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
|           | GRAFTON® Crunch®                 | DBM fibers with demineralized cortical cubes | Packable graft                        | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
|           | GRAFTON® Flex®                   | DBM fiber technology                         | Various sizes of flexible sheets      | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
|           | GRAFTON® Gel                     | DBM in a syringe                             | MIS and Percutaneous injectable graft | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
|           | GRAFTON® Matrix PLF              | DBM fiber technology                         | Single and double troughs             | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
|           | GRAFTON® Matrix Scoliosis Strips | DBM fiber technology                         | Various sizes of strips               | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
|           | GRAFTON® Orthoblend Large Defect | DBM fibers with crushed cancellous chips     | Packable graft                        | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
|           | GRAFTON® Orthoblend Small Defect | DBM fibers with larger cancellous chips      | Packable moldable graft               | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |

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|---------------------------|--------------------------------|---|--|--|--|---|
| Osteotech                 | GRAFTON Plus® Paste            | DBM in a syringe  | Injectable MIS graft, resists irrigation   | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
|                           | GRAFTON® Putty                 | DBM fiber technology  | Packable moldable graft  | <ul style="list-style-type: none"> <li>Osteoinduction</li> <li>Osteoconduction</li> <li>Incorporation/ complete remodelling</li> <li>Osteogenesis when mixed with bone marrow aspirate or autogenous bone graft</li> </ul> | <ul style="list-style-type: none"> <li>Peer-reviewed published human studies (incl. Level I-II prospective studies)</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul> | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Graft Substitute</li> <li>Bone Graft Extender</li> <li>Bone Void Filler</li> </ul> |
| Regeneration Technologies | BioSet™                        | DBM combined with natural gelatin carrier                                       | Injectable paste, injectable putty, strips and blocks with cortical cancellous chips | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Every lot tested <i>in vivo</i> for osteoinduction</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
| Smith & Nephew            | VIAGRAF                        | DBM combined with glycerol  | Putty, paste, gel, crunch and flex   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> </ul>   | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
| Stryker Biotech           | OP-1® Implant                  | rhBMP-7 with Type-1 bone collagen   | Lyophilized powder reconstituted with saline to form wet sand-like consistency       | <ul style="list-style-type: none"> <li>Bioresorbable scaffold</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies (Level I data)</li> <li>Case reports</li> <li>Animal studies</li> </ul>   | <ul style="list-style-type: none"> <li>HDE approval for long bone nonunions</li> </ul>  |
|                           | OP-1® Putty                    | rhBMP-7 with Type-1 bone collagen plus carboxymethyl-cellulose (putty additive) | Lyophilized powder reconstituted with saline to form wet sand-like consistency       | <ul style="list-style-type: none"> <li>Bioresorbable scaffold</li> <li>Osteoinduction</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies (Level I data)</li> <li>Case reports</li> <li>Animal studies</li> </ul>   | <ul style="list-style-type: none"> <li>HDE approval for revision posterolateral lumbar fusion</li> </ul>                                      |
| Synthes                   | Calceon® 6                     | Calcium sulfate   | Pellets  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> </ul>   | 510(k) cleared  |
|                           | chronOS®                       | β-TCP   | Granules, blocks and wedges  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Animal studies</li> </ul>   | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
|                           | Norian® SRS®                   | Calcium phosphate   | Injectable paste   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |
|                           | Norian® SRS® Fast Set Putty    | Calcium phosphate   | Moldable putty   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared <ul style="list-style-type: none"> <li>Bone Void Filler</li> </ul>   |

β-TCP - β-tricalcium phosphate      CCC - Cortical cancellous chips      HA/CC - Hydroxyapatite/calcium carbonate  
 CBM - Cancellous bone matrix      DBM - Demineralized bone matrix

PMA – Pre-Market Application; HDE – Humanitarian Device Exemption

| Company                   | Commercially available product           | Composition   | Commercially available forms  | Claimed mechanisms of action  | Burdens of proof  | FDA status   |
|---------------------------|--|---|---|---|---|--|
| Wright Medical Technology | ALLOMATRIX®                              | DBM with/without CBM in surgical grade calcium sulfate powder                       | Various volumes of injectable/ formable putty                       | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>  | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Cell culture</li> </ul>   | 510(k) cleared<br>• Bone Void Filler   |
|                           | ALLOMATRIX® RCS                          | DBM with CACIPLEX™ technology in surgical grade calcium sulfate powder              | Various volumes of formable putty                                   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>  | <ul style="list-style-type: none"> <li>Animal studies</li> </ul>  | 510(k) cleared<br>• Bone Void Filler   |
|                           | ALLOPURE™                                | Sterile femoral/tibial allograft  | 12mm Evans wedge<br>6mm Cotton wedge                                | <ul style="list-style-type: none"> <li>Osteoconduction</li> </ul>   | <ul style="list-style-type: none"> <li>Mechanical Testing</li> </ul>  | <ul style="list-style-type: none"> <li>100% derived from allograft tissue</li> <li>Regulated under 21 CFR Parts 1270 and 1271 as a human tissue</li> </ul> |
|                           | CANCELLO-PURE® Wedges                    | Bovine bone   | 10mm x 50mm wedge<br>12mm Evans wedge<br>6mm Cotton wedge           | <ul style="list-style-type: none"> <li>Osteoconduction</li> </ul>   | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared<br>• Bone Void Filler   |
|                           | CELLPLEX®                                | β-TCP   | Various sized granules  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>  | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared<br>• Bone Void Filler   |
|                           | IGNITE®                                  | DBM in surgical grade calcium sulfate powder to be mixed with bone marrow aspirate  | Percutaneous graft for problem fractures                            | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>  | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> <li>Cell culture</li> </ul>   | 510(k) cleared<br>• Bone Void Filler   |
|                           | MIIG® X3                                 | High strength surgical grade calcium sulfate  | Minimally invasive injectable graft for compression fractures       | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>  | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>   | 510(k) cleared<br>• Bone Void Filler   |
|                           | OSTEOSET®                                | Surgical grade calcium sulfate  | Various sized pellets   | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> </ul>  | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>   | 510(k) cleared<br>• Bone Void Filler   |
|                           | PRO-DENSE® Injectable Regenerative Graft | 75% calcium sulfate and 25% calcium phosphate                                       | Procedure kits, various volumes of injectable paste                 | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Dense bone regeneration</li> </ul>   | <ul style="list-style-type: none"> <li>Human studies</li> <li>Case reports</li> <li>Animal studies</li> </ul>   | 510(k) cleared<br>• Bone Void Filler   |
|                           | PRO-STIM™ Injectable Inductive Graft     | 50% calcium sulfate, 10% calcium phosphate, and 40% DBM by weight                   | Procedure kits, various volumes of injectable paste/ formable putty | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>  | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared<br>• Resorbable calcium salt bone void filler device  |
| Zimmer                    | CopiOs® Bone Void Filler                 | Dibasic calcium phosphate and Type-1 collagen                                       | Sponge and paste  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Accelerated healing vs. autograft</li> <li>Bioresorbable</li> <li>Osteogenesis and osteoinduction when mixed with bone marrow aspirate</li> </ul> | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared<br>• Bone Void Filler: Must be used with autologous blood products like blood or bone marrow  |
|                           | CopiOs® Cancellous Bone Graft            | Bovine bone   | Cancellous chips, cancellous cubes and cortico-cancellous wedges    | <ul style="list-style-type: none"> <li>Osteoconduction</li> </ul>   | <ul style="list-style-type: none"> <li>Case reports</li> <li>Animal studies</li> </ul>  | 510(k) cleared<br>• Bone Void Filler   |
|                           | Puros® DBM                               | Allograft DBM putty (putty with chips includes allograft chips from the same donor) | Putty and putty with chips  | <ul style="list-style-type: none"> <li>Osteoconduction</li> <li>Bioresorbable</li> <li>Osteoinduction</li> </ul>  | <ul style="list-style-type: none"> <li>Every lot tested in an <i>in vivo</i> rat assay for osteoinductive potential demonstrating bone formation in an ectopic model</li> </ul> | <ul style="list-style-type: none"> <li>100% derived from allograft tissue</li> <li>Regulated under 21 CFR Parts 1270 and 1271 as a human tissue</li> </ul> |

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