

Summary of typical bone-graft substitutes that are commercially available - 2008

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"> • Osteoconduction • Bioresorbable • Osteoinduction 	<ul style="list-style-type: none"> • Case reports • Animal studies • Cell culture 	• 510(k) cleared
Biomet Osteobiologics	ProOsteon® 500R	Coralline-derived hydroxyapatite/calcium carbonate (HA/CC) composite	Granular or block	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable 	<ul style="list-style-type: none"> • Human studies • Case reports • Animal studies 	• 510(k) cleared
	InterGro®	DBM in a lecithin carrier	Paste, putty and mix with HA/CC composite granules	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable • Osteoinduction 	<ul style="list-style-type: none"> • Case reports • Animal studies • Every lot tested for osteoinduction 	• 510(k) cleared
	BonePlast®	Calcium sulfate with or without HA/CC composite granules	Various volumes of powder and setting solution	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable 	<ul style="list-style-type: none"> • Case reports • Animal studies 	• 510(k) cleared
DePuy Spine	HEALOS® Bone Graft Replacement	Mineralized collagen matrix	Variety of strip sizes	<ul style="list-style-type: none"> • Osteoconduction • Creeping substitution • Osteoinduction • Osteogenesis when mixed with bone marrow aspirate 	<ul style="list-style-type: none"> • Peer-reviewed, published human studies • Case reports • Animal studies 	• 510(k) cleared
	CONDUIT® TCP Granules	100% β-TCP	Granules	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable 	<ul style="list-style-type: none"> • Case reports • Animal studies 	• 510(k) cleared
Exactech	Opteform®	DBM and cortical cancellous chips suspended in gelatin carrier	Formable putty or dry powder ready to be hydrated with autologous diluents or saline	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable • Osteoinduction • Osteogenesis when mixed with autogenous bone graft 	<ul style="list-style-type: none"> • Human studies • Case reports • Animal studies • Every lot tested <i>in vivo</i> for osteoinduction 	• 510(k) cleared
	Optefil®	DBM suspended in gelatin carrier	Injectable bone paste, dry powder ready to be hydrated with blood or saline	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable • Osteoinduction • Osteogenesis when mixed with autogenous bone graft 	<ul style="list-style-type: none"> • Human studies • Case reports • Animal studies • Every lot tested <i>in vivo</i> for osteoinduction 	• 510(k) cleared
	Optecure®	DBM suspended in a hydrogel carrier	Dry mix kit delivered with or buffered saline mix with patient's autogenous bone graft or autologous diluents	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable • Osteoinduction • Osteogenesis when mixed with autogenous bone graft 	<ul style="list-style-type: none"> • Human studies • Case reports • Animal studies • Every lot tested <i>in vivo</i> for osteoinduction 	• 510(k) cleared
	Optecure® + CCC	DBM and CCC suspended in a hydrogel carrier	Dry mix kit delivered with buffered saline or mix with patient's autogenous bone graft or autologous diluents	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable • Osteoinduction • Osteogenesis when mixed with autogenous bone graft 	<ul style="list-style-type: none"> • Animal studies • Every lot tested <i>in vivo</i> for osteoinduction 	• 510(k) cleared
	OpteMx™	HA/TCP biphasic combination	Granules, sticks, rounded wedges, wedges and cylinders in several sizes	<ul style="list-style-type: none"> • Osteoconduction • Bioresorbable • Compressive strength of 400psi • Osteogenesis and limited osteoinduction when mixed with bone marrow aspirate 	<ul style="list-style-type: none"> • Human studies • Case reports • Animal studies 	• 510(k) cleared

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Integra Orthobiologics/ (IsoTis Orthobiologics)	Accell 100™	DBM putty	Injectable putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Human studies Case reports Animal studies Every DBM lot tested for osteoinduction 	<ul style="list-style-type: none"> 510(k) cleared
	Accell Connexus®	DBM plus reverse phase medium	Injectable putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Human studies Case reports Animal studies Every DBM lot tested for osteoinduction 	<ul style="list-style-type: none"> 510(k) cleared
	Accell TBM™	Total bone matrix, 100% preformed	Various sized strips	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Human studies Case reports Animal studies Every DBM lot tested for osteoinduction 	<ul style="list-style-type: none"> 510(k) cleared
	Integra Mozaik™	<ul style="list-style-type: none"> 80% highly purified B-TCP 20% highly purified type-1 collagen 	Strip and putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Animal studies Case reports 	<ul style="list-style-type: none"> 510(k) cleared
LifeNet Health	Optium DBM®	DBM combined with glycerol carrier	Formable putty (bone fibers) and injectable gel (bone particles)	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Human studies Case reports Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
	IC Graft Chamber®	DBM particles and cancellous chips	Lyophilized and packaged in various sizes within a delivery chamber	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction Designed to be used with blood, PRP or bone marrow to enhance DBM activity. 	<ul style="list-style-type: none"> Animal studies Case reports 	<ul style="list-style-type: none"> Regulated under CFR 1270 and 1271 as a human tissue and 510(k) cleared
	Cellect DBM®	DBM fibers and cancellous chips	Provided in a specialized cartridge	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction Designed for the retention of osteoprogenitor cells 	<ul style="list-style-type: none"> Animal studies Case reports 	<ul style="list-style-type: none"> Regulated under CFR 1270 and 1271 as a human tissue and 510(k) cleared
Medtronic Spinal & Biologics	INFUSE® Bone Graft	rhBMP-2 protein on an absorbable collagen sponge	Multiple kit sizes	<ul style="list-style-type: none"> Bioresorbable carrier Osteoinduction Chemotaxis of stem cells; indirect osteogenesis 	<ul style="list-style-type: none"> Human studies (Level I and Level III data) Case reports Animal studies 	<ul style="list-style-type: none"> PMA approved for fusion with spinal cage PMA approved for open tibia fractures with IM nail
	MasterGraft® Granules	Biphasic calcium phosphate	Granules	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
	MasterGraft® Matrix	Calcium phosphate and collagen	Compression resistant block	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
	MasterGraft® Putty	Calcium phosphate and collagen	Moldable putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Animal studies 	<ul style="list-style-type: none"> 510(k) cleared

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Medtronic Spinal & Biologics	Progenix™ DBM Putty	DBM in Type-1 bovine collagen and sodium alginate	Ready to use injectable putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
	Osteofil® DBM	DBM in porcine gelatin	Injectable paste and moldable strips	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Animal studies Case reports 	<ul style="list-style-type: none"> 510(k) cleared
MTF/Synthes	DBX®	DBM in sodium hyaluronate carrier	Paste, putty mix and strip	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Human studies Case reports Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
NovaBone/MTF	NovaBone®	Bioactive silicate	Particulate and putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteostimulation 	<ul style="list-style-type: none"> Case reports Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
Orthovita	Vitoss®	100% β-TCP and 80% β-TCP/20% collagen	Putty, strip, flow, morsels and shapes	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Published human studies Case reports Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
Osteotech	Grafton®	DBM combined with Glycerol	Formable putty, injectable gel, putty mixed with chips, flexible sheets and matrix	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Published human studies Case reports Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
	Grafton Plus®	DBM combined with a starch carrier	Paste	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Case reports Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
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"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Human studies Case reports Animal studies Every lot tested <i>in vivo</i> for osteoinduction 	<ul style="list-style-type: none"> 510(k) cleared
Smith & Nephew	VIAGRAF	DBM combined with glycerol	Putty, paste, gel, crunch and flex	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Animal studies 	<ul style="list-style-type: none"> 510(k) cleared
Stryker Biotech	OP-1® Implant	rhBMP-7 with type 1 bone collagen	Lyophilized powder reconstituted to form wet sand	<ul style="list-style-type: none"> Bioresorbable scaffold Osteoinduction 	<ul style="list-style-type: none"> Human studies (Level I data) Case reports Animal studies 	<ul style="list-style-type: none"> HDE approval for long bone nonunions
	OP-1® Putty	rhBMP-7 with type 1 bone collagen	Lyophilized powder reconstituted to form putty	<ul style="list-style-type: none"> Bioresorbable scaffold Osteoinduction 	<ul style="list-style-type: none"> Human studies (Level I data) Case reports Animal studies 	<ul style="list-style-type: none"> HDE approval for revision posterolateral fusion
	Calstrux™	Tricalcium phosphate with carboxy-methylcellulose	Moldable putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Animal studies 	<ul style="list-style-type: none"> 510(k) cleared

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Synthes	Norian® SRS®	Calcium phosphate	Injectable paste	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Human studies Case reports Animal studies 	• 510(k) cleared
	Norian® SRS® Fast Set Putty	Calcium phosphate	Moldable putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Human studies Case reports Animal studies 	• 510(k) cleared
	chronOS®	β-tricalcium phosphate	Granules, blocks and wedges	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Animal studies 	• 510(k) cleared
	Calceon® 6	Calcium sulfate	Pellets	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Animal studies 	• 510(k) cleared
Wright Medical Technology	OSTEOSET®	Surgical grade calcium sulfate	Various sized pellets	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Human studies Case reports Animal studies 	• 510(k) cleared
	MIIG® X3	High strength surgical grade calcium sulfate	Minimally invasive injectable graft for compression fractures	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Human studies Case reports Animal studies 	• 510(k) cleared
	CELLPLEX®	Tricalcium phosphate	Various sized granules	<ul style="list-style-type: none"> Osteoconduction Bioresorbable 	<ul style="list-style-type: none"> Case reports Animal studies 	• 510(k) cleared
	ALLOMATRIX®	DBM with/without CBM in surgical grade calcium sulfate powder	Various volumes of injectable/ formable putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Human studies Case reports Animal studies Cell culture 	• 510(k) cleared
	ALLOMATRIX® RCS	DBM with CACIPLEX™ Technology in surgical grade calcium sulfate powder	Various volumes of formable putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Animal studies 	• 510(k) cleared
	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"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Human studies Case reports Animal studies Cell culture 	• 510(k) cleared
Zimmer	CopiOs® Bone Void Filler	Dibasic calcium phosphate and Type I collagen	Sponge and paste	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteogenesis and osteoinduction when mixed with bone marrow aspirate 	<ul style="list-style-type: none"> Case reports Animal studies 	• 510(k) cleared
	CopiOs® Cancellous Bone Graft	Bovine bone	Cancellous chips, cancellous cubes and wedges	<ul style="list-style-type: none"> Osteoconduction 	<ul style="list-style-type: none"> Case reports Animal studies 	• 510(k) cleared
	Puros® Demineralized Bone Matrix	DBM putty	Putty	<ul style="list-style-type: none"> Osteoconduction Bioresorbable Osteoinduction 	<ul style="list-style-type: none"> Every lot tested <i>in vivo</i> for osteoinduction 	<ul style="list-style-type: none"> 100% derived from allograft tissue FDA clearance not required