Grafting Options

	CATEGORIZATION	CHARACTERISTICS	REGULATORY PATHWAY AND CLINICAL BURDEN OF PROOF	EXAMPLES
Recombinant Growth Factors	Proven alternative to Autograft[1]	True biologic: Combination products with consistent, highly active signal proteins that drive bone regeneration[4]	Pre-Market Approval (PMA) Safety and Efficacy in large pivotal clinical trial[5]	AUGMENT® Bone Graft (rhPDGF-BB/β-TCP) INFUSE® Bone Graft (rhBMP-2/ACS)
Allograft Tissue	Bone Void Fillers[2]	Osteoconductive and weakly osteoinductive putties with variable handling Cell-containing products include various claims of cell viability at point of use	Human tissue products (361 HCT/Ps) – No proof needed[6] Devices containing human tissue (351 HCT/Ps - more than minimally manipulated) – 510(k)[7]	DBX®, TRINITY® Elite, ACCELL®, ALLOMATRIX®, OSTEOCEL® Plus, GRAFTON®, BIO4®, OSTEOSPONGE®, FUSIONFLEX®, Allograft chips, femoral head allograft, ALLOPURE® wedges
Synthetic Scaffolds	Bone Void Fillers[3]	Passive osteoconduction and fills space	Synthetics – 510(k)[7]	VITOSS® BA, HYDROSET®, NORIAN® Drillable Inject, OSTEOSET®

1. Combination Growth Factor products composed of biologically active signals that promote chemotaxis, mitogenesis, angiogenesis, and/or osteoinductivity, rigorously reviewed by FDA and proven to be non-inferior to the Gold Standard, autograft in specific approved indications (see back page).
2. Void fillers with mineralized or demineralized bone, with or without cryopreserved cells from same donor intended for treatment of musculoskeletal defects.
3. Physical scaffolds composed of synthetic materials (e.g. calcium phosphate) intended to be used to fill bone voids.
4. Platelet-derived growth factor (rhPDGF-BB) and bone morphogenetic protein-2 (rhBMP-2) have been tested, reviewed and established as alternatives to autograft in multiple clinical studies for specific indications in foot & ankle (rhPDGF-BB only), spine/orthopaedic trauma (rhBMP-2 only) and dental (rhPDGF-BB & rhBMP-2).
5. Multiple clinical trials culminating in a large pivotal trial are typically required to prove that the combination device is both safe and efficacious in the specified indications.
6. Human tissues designated as 361 HCT/Ps are not regulated as medical devices and do not require a submission and/or review for commercialization. Tissue processors are required to register with FDA and follow Good Tissue Practices (GTP) per 21 CFR 1271.
7. A 510(k) clearance demonstrates that the device is substantially equivalent to a legally marketed device.