

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 1000160576	Other FDA Registrations: Blood: Devices: FEI: 0002029012 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2021 Last Registration Receipt Date: 11/18/2020 Summary Report Print Date: 11/30/2020
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Legal Name and Location: Interpore Cross International, LLC (DBA Zimmer Biomet Irvine) 181 Technology Drive, Suite 100 Irvine, California 92618 USA Phone: 949-453-3200 Ext.: 211	Reporting Official: Phil Mellinger, Senior Director,R&D/Tissue Bank 181 Technology Drive, Suite 100 Irvine, California 92618 USA Phone: 949-453-3200 Ext. 211 Phil.mellinger@zimmerbiomet.com	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: No Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone					X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Bonus CC Matrix, RegenerOSS Putty, RegenerOSS Plus, StaGraft Putty,
StaGraft Plus, StaGraft Paste, StaGraft Cancellous,
Indux Cancellous, Indux Cortical, Allogenix Plus,
Allogenix Putty, InterGro Fiber DBM, Bonus II, Equivabone,
Bonus Fiber DBM, VerteGen

Proprietary Name(s):	Bone	PrimaGen Advanced Allograft, Stagraft Fiber DBM, Cellentra, InterGro Putty, InterGro Paste, InterGro Plus, Bonus Triad
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