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**

Ext.:

FEI: 1000160576

Other FDA Registrations: Blood:

Devices:FEI: 0002029012

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/17/2023 Summary Report Print Date: 12/01/2023

No

Legal Name and Location:

Interpore Cross International, LLC (DBA Zimmer Biomet Irvine)

181 Technology Drive, Suite 100

Irvine, California 92618

Phone: 949-453-3211

USA

181 Technology Drive, Suite 100

Phil Mellinger, Senior Director, R&D/Tissue Bank

Irvine, California 92618

Reporting Official:

Phone: 949-453-3211 Ext. Phil.mellinger@zimmerbiomet.com Satellite Recovery Establishment:

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)).

	Establishment Functions											
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone					Х	Х	Х	Х	Х			***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												

FEI:

Additional Informatio	n: RegenerOSS Putty Plus, StaGraft	Putty,							
	StaGraft Plus, StaGraft Paste, Sta	StaGraft Plus, StaGraft Paste, StaGraft Cancellous,							
	Allogenix Plus, Allogenix Putty, Int	Allogenix Plus, Allogenix Putty, InterGro Fiber DBM,							
	Equivabone								
Proprietary Name(s):	Bone	PrimaGen Advanced Allograft, Stagraft Fiber DBM, InterGro Putty, InterGro Paste, InterGro Plus, Bonus Triad							

FEI: 1000160576 Legal Name: Interpore Cross International, LLC (DBA Zimmer Biomet Irvine)