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: 2025 Last Registration Receipt Date: 11/22/2024 Summary Report Print Date: 12/05/2024

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												

Proprietary Name(s):	Bone	StaGraft Fiber DBM, InterGro Fiber DBM

Legal Name:

Interpore Cross International, LLC (DBA Zimmer Biomet Irvine)

Additional Information:

1000160576

FEI: