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: 3005168462

Other FDA Registrations: Blood:

Devices:FEI: 3005031160

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/09/2023 Summary Report Print Date: 12/15/2023

Legal Name and Location:

Belgrade, Montana 59714

Phone: 406-924-5878

USA

Xtant Medical Holdings, Inc. 664 Cruiser Lane

Ext.:

Reporting Official:

Rebecca L Lennemann, VP of Quality and Regulatory Affairs

664 Cruiser Lane

Belgrade, Montana 59714

Phone: 406-924-5878 Ext. rlennemann@xtantmedical.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)).

	Donor Type(s)	Establishment Functions										
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane							Х		Х			Dual layer membrane
Blood Vessel												
Bone			Х		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			Х		Х	Х	Х	Х	Х			Connective Tissue
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):	Bone	Traditional Allografts, OsteoSponge, OsteoWrap, OrbitalWrap, Milled Precision Allografts, 3Demin, BacFast HD, Atrix-C, Atrix-C Union, OsteoVive, OsteoVive Plus, OsteoFactor, OsteoMax. FiberOS, Hydragraft, BOB BEAST, Influx

FEI: 3005168462 Legal Name: Xtant Medical Holdings, Inc.

Additional Information:

No additional information provided.