

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: Change in Information Last Annual Registration Year: 2024 Last Registration Receipt Date: 08/15/2024 Summary Report Print Date: 09/12/2024
--	------------------------	--	---

Legal Name and Location: Xtant Medical Holdings, Inc. 664 Cruiser Lane Belgrade, Montana 59714 USA Phone: 406-924-5878 Ext.:	Reporting Official: Rebecca L Lennemann, VP of Quality and Regulatory Affairs 664 Cruiser Lane Belgrade, Montana 59714 USA 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)).
---	--	--

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			X		X	X	X	X	X			***See full text on next page.
Blood Vessel												
Bone			X		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			X		X	X	X	X	X			Connective Tissue
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):	Amniotic Membrane	Dual layer membrane, Single layer membrane, SimpliMax, SimpliGraft, BioSport Amniotic Membrane, Amnio-Maxx
	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, BEAST Plus, Influx, Isto Plus OsteoSelect, OsteoSelect Plus, Elemax, Bioaset, BioAdapt Foam, BioAdapt Bridge, FibreX, Bigfoot, Reficio, ProSpace, Curigraft, VIA, Maxx-Fuse, Magnus

FEI: 3005168462

Legal Name:

Xtant Medical Holdings, Inc.