

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10</b>		FEI: 1000592496		Other FDA Registrations: <b>Blood:</b> <b>Devices:</b> FEI: 0001060818 <b>Drugs:</b>		Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/18/2024 Summary Report Print Date: 12/05/2024						
<b>Legal Name and Location:</b>  BioHorizons Implant Systems Inc. 2300 Riverchase Center   Birmingham, Alabama 35244 USA  Phone: 205-967-7880  <b>Ext.:</b> N/A		<b>Reporting Official:</b>  Jared O Cooper, Sr. Director, Regulatory Affairs 2300 Riverchase Center Birmingham, Alabama 35244 USA Phone: 205-967-7880 Ext. 7994 jcooper@biohorizons.com				<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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			Mem-lok Amnio
Blood Vessel												
Bone							X		X			MinerOss, Grafton, Genate
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							X		X			Mem-Lok Pericardium
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X		X			***See full text on next page.
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** No additional information provided.

<b>Proprietary Name(s):</b>	Skin	AlloDerm Select, AlloDerm Select GBR, AlloDerm SELECT THICK RTM
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