

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: 1000148471	Other FDA Registrations: Blood: Devices: FEI: 1000148471 Drugs:	Reason For Last Submission: Change in Information Last Annual Registration Year: 2025 Last Registration Receipt Date: 07/21/2025 Summary Report Print Date: 07/22/2025
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Legal Name and Location: Organogenesis Inc. 150 Dan Road Canton, Massachusetts 02021 USA Phone: 781-401-1155 Ext.:	Reporting Official: Patrick R Bilbo, Chief Operating Officer 150 Dan Road Canton, Massachusetts 02021 USA Phone: 781-401-1155 Ext. Regulatory@organo.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)).
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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			***See full text on next page.
Blood Vessel												
Bone							X		X			FiberOS, OCOMP
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												

Additional Information: No additional information provided.

Proprietary Name(s):	Amniotic Membrane	Affinity, NuShield, NuForm, Novachor, CYGNUS Dual, CYGNUS Matrix, VIA Matrix, SimpliGraft, SimpliMax
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