

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: 3006638648	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/15/2023 Summary Report Print Date: 12/01/2023
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Legal Name and Location: Osiris Therapeutics, Inc. 7015 Albert Einstein Drive Columbia, Maryland 21046 USA Phone: 443-545-1800 Ext.:	Reporting Official: Karen Merritt, Quality Director 7015 Albert Einstein Dr. Columbia, Maryland 21046 USA Phone: 609-915-3514 Ext. Karen.Merritt@smith-nephew.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	X	X	X	X	X	X			***See full text on next page.
Blood Vessel												
Bone			X	X	X			X	X			BIO4
Cardiac Tissue - non-valved												
Cartilage			X	X	X			X	X			Cartiform
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		X	X	X	X	X	X	X	X			***See full text on next page.

Additional Information: Osiris Therapeutics, Inc. is the legal entity and is a wholly owned subsidiary of Smith & Nephew Consolidated, Inc.

Proprietary Name(s):	Amniotic Membrane	GRAFIX PRIME; GRAFIX CORE; GRAFIX XC; GRAFIX PL PRIME, GRAFIX PLUS, GRAFIX PL XC
	Umbilical Cord Tissue	STRAVIX; STRAVIX PL; STRAVIX MESHED

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