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| 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: 2025 Last Registration Receipt Date: 11/21/2024 Summary Report Print Date: 12/05/2024 |
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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, Sr. Director, Quality 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.

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| 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 |

FEI: 3006638648

Legal Name:

Osiris Therapeutics, Inc.