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

Ext.:

FEI: 3032905890

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Change in Information
Last Annual Registration Year: 2025
Last Registration Receipt Date: 01/06/2025
Summary Report Print Date: 01/10/2025

No

Legal Name and Location:

OX BioMed LLC

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USA

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Reporting Official:

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Satellite Recovery Establishment:

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)).

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane							Х		Х			***See full text on next page.
Blood Vessel												
Bone												
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							Х		Х			Derm-Maxx
Tendon								<u> </u>				
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Informatio	n: No additional information provided.	
Proprietary Name(s):	Amniotic Membrane	Amnio-maxx, Membrane Wrap, Membrane Wrap Hydro, Xcell Amnio Matrix, Xwrap, Xcellerate, NeoStim DL, NeoStim TL, Dermacyte AC Matrix

FEI: 3032905890 Legal Name: OX BioMed LLC