## 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: 1000511606

Other FDA Registrations:

Blood: Devices:

Drugs: FEI: 1000511606

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/10/2024 Summary Report Print Date: 12/20/2024

Legal Name and Location:

WuXi Apptec, Inc. 1265 Kennestone Circle

Ext.: 3223

Marietta, Georgia 30066 USA

Phone: 770-514-0262

Reporting Official:

Heather H Laird. QA Director 1265 Kennestone Circle Marietta, Georgia 30066

Phone: 770-514-0262 Ext. 3223 heather.laird@wuxiapptec.com

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only:

Yes

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)).

No

		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						
Blood Vessel						Х						
Bone						Х						
Cardiac Tissue - non-valved												
Cartilage						Х						
Cornea												
Dura Mater												
Embryo												
Fascia						Х						
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament						Х						
Nerve Tissue												
Oocyte												
Ovarian Tissue						Х						
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium						Х						
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin						Х						
Tendon						Х						
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue						Х						

Additional Information: Mi	crobiology testing is product only testing.
----------------------------	---

Proprietary Name(s):

FEI: 1000511606 Legal Name: WuXi Apptec, Inc.