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: 3015471646

Reporting Official:

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2024
Last Registration Receipt Date: 11/17/2023
Summary Report Print Date: 12/01/2023

Legal Name and Location:

Halfmoon, New York 12065

Phone: 716-529-4300

Upstate New York Transplant Services, Inc.

11c Solar Drive

USA

Christina M Joyce, Director of Quality 4444 Bryant and Stratton Way Williamsville , New York 14221

USA

Phone: 716-529-4324 Ext. Cjoyce@connectlife.org

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)).

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

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Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3015471646 Legal Name: Upstate New York Transplant Services, Inc.