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: 3005459045

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/30/2024 Summary Report Print Date: 01/10/2025

Legal Name and Location:

ATSF NW Office 1733 Westgate Road

Eau Claire, Wisconsin 54703

USA

Phone: 715-831-8428

Ext.:

Reporting Official:

Angela L Georgalis, Director of Quality Systems

7900 N. 70th Ave.

Unit 106

Glendale, Arizona 85303

Phone: 602-900-0513 Ext. ageorgalis@atsfoundation.org 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)).

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

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3005459045 Legal Name: ATSF NW Office