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: 3005463425

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2021
Last Registration Receipt Date: 11/24/2020
Summary Report Print Date: 11/30/2020

Legal Name and Location:

ATSF NE Office

1113 W. Kennedy Avenue Suite C

Kimberly, Wisconsin 54136

USA

Phone: 920-738-6620

Reporting Official:

Jennifer D Drago, Director of Quality Systems

7900 N. 70th Ave.

Unit 106

Glendale, Arizona 85303

USA

Phone: 602-900-0513 Ext. jdrago@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

	Donor Type(s)	Establishment Functions										
HCT/P(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		Х	Х				Х					
Heart Valve		Х	Х									
HPC Apheresis												
HPC Cord Blood												
Ligament		Х	Х				Х					
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		Х	Х				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												

Additional Information:	No additional information provided.
Additional information.	ino additional inionnation provided

Proprietary Name(s):

FEI: 3005463425 Legal Name: ATSF NE Office