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: 3016003966

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025

Last Registration Receipt Date: 11/15/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

Cordova, Tennessee 38018

Phone: 901-254-8393

USA

Samaritan Biologics, LLC 241 Germantown Bend Cove Reporting Official: Jerry Y Chang, Managing Partner 241 Germantown Bend Cove Cordova, Tennessee 38018

Phone: 352-256-2707 Ext. jchang@samaritanbiologics.com 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			***See full text on next page.	
Blood Vessel													
Bone							Х		X			***See full text on next page.	
Cardiac Tissue - non-valved													
Cartilage													
Cornea													
Dura Mater													
Embryo													
Fascia							Х		X				
Heart Valve													
HPC Apheresis													
HPC Cord Blood													
Ligament													
Nerve Tissue													
Oocyte													
Ovarian Tissue													
Pancreatic Islet Cells - autologous													
Parathyroid													
Pericardium							Х		Х				
Peripheral Blood Mononuclear Cells													
Peritoneal Membrane													
Sclera													
Semen													
Skin							Х		Х			***See full text on next page.	
Tendon							Х		Х				
Testicular Tissue													
Tooth Pulp													
Umbilical Cord Tissue										30-MAY-21			

Additional Information:	No additional information provided.

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Pro	prietary	name	5):

s):	Amniotic Membrane	Revival FT, Cygnus, AmnioStratis FT, MLG-Complete, EyeGen, EyeGen FT, SamariDent-FT, Retain FT, SurPatch, SurPatch-F, Complete FT, Complete SL, Complete ACA, Complete AA, MLG Complete Woundcare, Singlay, DuoAmnion, Total, Most
	Bone	F3, F3 DBM, BioFit, F-3 Graft Collar, OsteoGro-V, OsteoGro
	Skin	SimpliDerm-SB, SimpliDerm, Surgenex Skin

FEI: 3016003966 Legal Name: Samaritan Biologics, LLC