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: 2023 Last Registration Receipt Date: 10/23/2023 Summary Report Print Date: 11/15/2023

Legal Name and Location:

Samaritan Biologics, LLC 241 Germantown Bend Cove

Cordova, Tennessee 38018

Phone: 901-254-8393

USA

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)).

	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							Х		Х			***See full text on next page.
Blood Vessel												
Bone							Х		Х			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia							Х		Х			
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		

roprietary Name(s):	Amniotic Membrane	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

Additional Information:

Skin

No additional information provided.

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SimpliDerm-SB, SimpliDerm, Surgenex Skin