## 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: 1000307504

Other FDA Registrations: Blood:

Devices: Drugs:

Fatablish mant Frontier

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025
Last Registration Receipt Date: 11/26/2024
Summary Report Print Date: 12/05/2024

Legal Name and Location:

DCI Donor Services Tissue Bank

566 Mainstream Dr. Suite 300

Nashville, Tennessee 37228

USA

Phone: 615-234-5200

Reporting Official:

Carrie S Crocker, Sr. Director, GTP Quality Systems

566 Mainstream Dr.

Suite 300

Nashville, Tennessee 37228

USA

Phone: 615-564-3774 Ext. carrie.crocker@dcids.org

Satellite Recovery Establishment:

No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:  $$\operatorname{No}$$ 

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

roprietary Name(s):	Amniotic Membrane	NuDYN DL; NuDYN DL Mesh; NuShield;Affinity;Novachor;					
	Bone	OSTEOAMP;OSSEOGEN;INFLUX;ALLOCELL;OCMP; MinerOss; Profuse; AlphaGRAFT;					

Changes in Proprietary Names. No additional changes
Proprietary Names: NuDYN DL, NuDYN DL Mesh, NuShield, Affinity, Novachor, OSTEOAMP, OSSEOGEN, INFLUX, ALLOCELL, OCMP, MinerOss, Mem-Lok, AlphaGRAFT,

Additional Information:

FEI: 1000307504 Legal Name: DCI Donor Services Tissue Bank