## 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: 3010056221

Other FDA Registrations:

Blood: Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2019 Last Registration Receipt Date: 05/14/2019 Summary Report Print Date: 06/14/2019

Legal Name and Location:

GenCure Tissue Center 6211 IH-10 West

Reporting Official:

Becky M Cap, Chief Operating Officer

6211 IH-10 West San Antonio, Texas 78201

USA

Phone: 210-731-5586 Ext. becky.cap@gencure.org

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)).

San Antonio, Texas 78201 Phone: 210-731-5569

Ext.:

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

Establishment Functions

Additional Information:

No additional information provided.

Proprietary Name(s):

FEI: 3010056221

Legal Name: