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: 3003567004

Other FDA Registrations: Blood:

Devices: Drugs: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2023 Last Registration Receipt Date: 01/04/2023 Summary Report Print Date: 01/05/2023

Legal Name and Location:

Regenerative Biologics, Inc. 1901 NW 67th Place

Bay D

Gainesville, Florida 32653

USA

Phone: 352-248-2114

Reporting Official:

Lawrence Hopkins, Chief Executive Officer

6241 NW 23rd. St.

Suite 500

Gainesville, Florida 32653

USA

Phone: 352-248-2114 Ext. fcase@rbidonorcare.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000307669

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

Additional Information:	Regenerative Biologics,	, Inc. recovers amniotic fluid an	d umbilical cord blood

Proprietary Name(s):

FEI: 3003567004 Legal Name: Regenerative Biologics, Inc.