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: 3007952886

Other FDA Registrations: Blood:

Devices:FEI: 0010061463

Drugs:

Fatablish mant Frontier

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024
Last Registration Receipt Date: 10/08/2024
Summary Report Print Date: 11/15/2024

Legal Name and Location:

Parametrics Medical, LLC 1501 Leander Dr

Suite 140

Leander, Texas 78641

USA

Phone: 512-574-0886

Reporting Official:

Troy D Kokoszka, Director of Quality

1501 Leander Dr

Suite 140

Leander, Texas 78641

USA

Phone: 512-574-0886 Ext. quality@parametricsmedical.com

Satellite Recovery Establishment:

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)).

No

	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	Х			Restorigin, Procenta
Blood Vessel												
Bone							Х	Х	Х			Osteosource
Cardiac Tissue - non-valved												
Cartilage							Х	Х	Х			
Cornea												
Dura Mater												
Embryo												
Fascia							Х	Х	Х			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							Х	Х	Х			NoRad, LoRad, Coll-e-Strong
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium							Х	Х	Х			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							Х	Х	Х			Coll-e-Derm, Dermis On Demand
Tendon							Х	Х	Х			NoRad, LoRad, Coll-e-Strong
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue										12-JAN-23		

Procenta- Store and Distribute only

Proprietary Name(s):

FEI: 3007952886

Legal Name:

Parametrics Medical, LLC