

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: 0001870308	Other FDA Registrations: Blood: FEI: 0001870308 Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2018 Last Registration Receipt Date: 10/05/2018 Summary Report Print Date: 11/15/2018
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Legal Name and Location: South Bend Medical Foundation, Inc 530 N. Lafayette Boulevard South Bend, Indiana 46601-1098 USA Phone: 574-234-4716 Ext.: 4241	Reporting Official: Emily R Plenus, Supervisor of Quality Systems 530 N. Lafayette Boulevard South Bend, Indiana 46601-1098 USA Phone: 574-234-4176 Ext. 4241 eplenus@sbmf.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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel				X								
Bone				X								
Cardiac Tissue - non-valved												
Cartilage				X								
Cornea				X								
Dura Mater												
Embryo	Anonymous, Directed, SIP			X								
Fascia				X								
Heart Valve				X								
HPC Apheresis												
HPC Cord Blood												
Ligament				X								
Nerve Tissue												
Oocyte	Anonymous, Directed, SIP			X								
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium				X								
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera				X								
Semen	Anonymous, Directed, SIP			X								
Skin				X								
Tendon				X								
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):