

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: 2020  
Last Registration Receipt Date: 11/19/2019  
Summary Report Print Date: 12/10/2019

**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@sbfm.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)).

**Establishment Functions**

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				X								
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	Autologous, Family Related			X								
HPC Cord Blood	Autologous, Family Related			X								
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				X								

**Additional Information:** No additional information provided.

**Proprietary Name(s):**

FEI: 0001870308

Legal Name:

South Bend Medical Foundation, Inc