See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 6/30/2020

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 (HCT/Ps)

(See reverse side for instructions)

1. REGISTRATION NUMBER (FDA Establishment Identifier)
FEI: 0001870308

2. REASON FOR SUBMISSION
a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:29-NOV-2017
DISTRICT: Detroit
PRINTED BY FDA:13-DEC-2017

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. FEI: 0001870308
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
South Bend Medical Foundation, Inc
530 N. Lafayette Boulevard
South Bend, Indiana 46601-1098

a. PHONE 574-234-4716 EXT 4522
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)
South Bend Medical Foundation, Inc
Attn: Christine D. Saitz, BS, MLT (ASCP)
530 N. Lafayette Boulevard
South Bend, Indiana 46601-1098

a. PHONE 574-234-4176 EXT 4522

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Christine D. Saitz, BS, MLT (ASCP)
b. E-MAIL csaitz@sbmf.org
c. TITLE Director of Quality Systems d. DATE 29-NOV-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a. Bone			X						X			
b. Cartilage			X						X			
c. Cornea			X						X			
d. Dura Mater												
e. Embryo ☒ SIP ☒ Directed ☒ Anonymous			X						X			
f. Fascia			X						X			
g. Heart Valve			X						X			
h. Ligament			X						X			
i. Oocyte ☒ SIP ☒ Directed ☒ Anonymous			X						X			
j. Pericardium			X						X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera			X						X			
m. Semen ☒ SIP ☒ Directed ☒ Anonymous			X						X			
n. Skin			X						X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon			X						X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☒ Allogeneic			X								X	
r. Vascular Graft			X						X			
s. Placental Blood Derived Cells			X						X			
t. Amniotic Fluid			X						X			
u.												
v.												

FORM FDA - 3356 (7/17)