

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

1  
VALIDATION—FOR FDA USE ONLY

VALIDATED BY FDA:23-NOV-2016  
DISTRICT: Detroit  
PRINTED BY FDA:15-DEC-2016

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

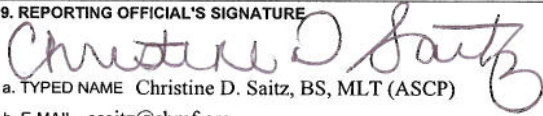
7. ENTER CORRECTIONS TO ITEM 6

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 22-NOV-2016

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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