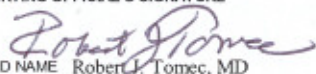


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) <i>(See reverse side for instructions)</i>		1. REGISTRATION NUMBER (Field Establishment Identifier) FE#: 0001870308	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:01-DEC-2009 DISTRICT: Detroit PRINTED BY FDA:02-DEC-2009	1																																																																																																																																																																																																																																																																																																																																													
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. _____		PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width: 30%;">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="width: 5%;">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="width: 5%;">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="width: 5%;">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2" style="width: 5%;">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr><td>a. Bone</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td></tr> <tr><td>c. Cornea</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>e. Embryo</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>f. 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Semen</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td></tr> <tr><td>n. Skin</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td></tr> <tr><td>o. Somatic Cell Therapy Products</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>p. Tendon</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td></tr> <tr><td>q. Umbilical Cord Blood Stem Cells</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td></tr> <tr><td>r. Vascular Graft</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td></tr> <tr><td>s.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>t.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>u.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>v.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>				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 DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)	Recover	Screen	Test	Package	Process	Store	Label	Distribute	a. Bone			X						X				b. Cartilage			X						X				c. 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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 1522 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> 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: Robert J. Tomec, MD 530 N. Lafayette Boulevard South Bend, Indiana 46601-1098 a. PHONE 574-234-4176 EXT _____																																																																																																																																																																																																																																																																																																																																																
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9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Robert J. Tomec, MD b. E-MAIL rtomec@sbfm.org c. TITLE President d. DATE 30-NOV-2009																																																																																																																																																																																																																																																																																																																																																		