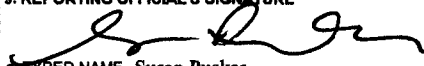


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3001239310	2. REASON FOR SUBMISSION a. <input checked="" type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input 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:05-SEP-2008 DISTRICT: Minneapolis PRINTED BY FDA:05-SEP-2008
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																																																																																																																																																																																																																																																																																																																																																																																	
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th rowspan="2" style="width:45%;">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="width:5%;">11. HCT/Ps DESCRIBED IN 21 CFR 1271.16</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> <tr> <td>No HCT / P Specified</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr><td>a. Bone</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>b. Cartilage</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>c. Cornea</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>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></tr> <tr><td>e. Embryo</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><input type="checkbox"/> SIP</td> <td><input type="checkbox"/> Directed</td> <td><input type="checkbox"/> Anonymous</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr><td>f. Fascia</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>g. Heart Valve</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>h. Ligament</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>i. Oocyte</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><input type="checkbox"/> SIP</td> <td><input type="checkbox"/> Directed</td> <td><input type="checkbox"/> Anonymous</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr><td>j. Pericardium</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>k. 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Vascular Graft</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>s.</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></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></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></tr> </table>	Types of HCT / Ps	Establishment Functions								11. HCT/Ps DESCRIBED IN 21 CFR 1271.16	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	No HCT / P Specified			X									a. Bone												b. Cartilage												c. Cornea												d. Dura Mater												e. 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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Medtox Laboratories Inc. 402 West County Road D St. Paul, Minnesota 55112 a. PHONE 651-636-7466 EXT _____ 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 <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Medtox Laboratories Inc. Attn: Susan Puskas 402 West County Road D St. Paul, Minnesota 55112 a. PHONE 651-636-7466 EXT _____	7. ENTER CORRECTIONS TO ITEM 6																																																																																																																																																																																																																																																																																																																																																																																	
8. U.S. AGENT a. E-MAIL _____	9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Susan Puskas b. E-MAIL spuskas@medtox.com c. TITLE VP Quality & Regulatory Affairs d. DATE 24-JUL-2008																																																																																																																																																																																																																																																																																																																																																																																	