

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3004586709	<b>2. REASON FOR SUBMISSION</b> 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  * 3004586709 * VALIDATED By FDA:12/10/07 PRINTED By FDA:12/17/07 DISTRICT: Florida
--	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION		14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																								
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <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" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</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 style="background-color: #cccccc;">No HCT / P Specified</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>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 <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td>X</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 <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td>X</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. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</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>l. Sclera</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>m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td>X</td><td></td> </tr> <tr> <td>n. Skin</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>o. Somatic Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</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></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</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>r. 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> </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	Recover	Screen	Test	Package	Process	Store	Label	Distribute	No HCT / P Specified												a. Bone												b. Cartilage												c. Cornea												d. Dura Mater												e. Embryo <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous						X			X	X		f. Fascia												g. Heart Valve												h. Ligament												i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous						X			X	X		j. Pericardium												k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												l. Sclera												m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous						X			X	X		n. Skin												o. Somatic Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												p. Tendon												q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												r. Vascular Graft												<b>11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</b> <b>12. HCT/Ps REGULATED AS MEDICAL DEVICES</b> <b>13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</b>	1
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																																																																																																																																																																																																																																													
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																			
No HCT / P Specified																																																																																																																																																																																																																																																											
a. Bone																																																																																																																																																																																																																																																											
b. Cartilage																																																																																																																																																																																																																																																											
c. Cornea																																																																																																																																																																																																																																																											
d. Dura Mater																																																																																																																																																																																																																																																											
e. Embryo <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous						X			X	X																																																																																																																																																																																																																																																	
f. Fascia																																																																																																																																																																																																																																																											
g. Heart Valve																																																																																																																																																																																																																																																											
h. Ligament																																																																																																																																																																																																																																																											
i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous						X			X	X																																																																																																																																																																																																																																																	
j. Pericardium																																																																																																																																																																																																																																																											
k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																											
l. Sclera																																																																																																																																																																																																																																																											
m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous						X			X	X																																																																																																																																																																																																																																																	
n. Skin																																																																																																																																																																																																																																																											
o. Somatic Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																											
p. Tendon																																																																																																																																																																																																																																																											
q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																											
r. Vascular Graft																																																																																																																																																																																																																																																											
<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> ReproTech, Ltd. 4760 West Commercial Blvd. Fort Lauderdale, Florida 33319  a. PHONE 954-332-6650 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<b>5. ENTER CORRECTIONS TO ITEM 4</b>																																																																																																																																																																																																																																																										
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> ReproTech, Ltd. Attn: Russell C. Bierbaum, MS 550 Village Center Drive STE 300 St Paul, Minnesota 55127  a. PHONE 651-489-0827 EXT 100	<b>7. ENTER CORRECTIONS TO ITEM 6</b>																																																																																																																																																																																																																																																										
<b>8. U.S. AGENT</b>  a. E-MAIL _____	<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Russell C. Bierbaum, MS b. E-MAIL rcbierbaum@reprot.com c. TITLE President d. DATE 07-DEC-2007																																																																																																																																																																																																																																																										

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**  
(Field Establishment Identifier)

FEI: 3004586709

2

**ADDITIONAL INFORMATION:**

We may also store ovarian tissue.

**Proprietary Name(s):**