

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> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3003347229	<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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:16-NOV-2017 DISTRICT: Kansas City PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																								
<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="9">Establishment Functions</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">11. HCT/Ps DESCRIBED IN 21 OF 171.10</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> <th rowspan="2" style="width:15%;">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> </table>	Types of HCT / Ps	Establishment Functions									11. HCT/Ps DESCRIBED IN 21 OF 171.10	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		
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<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Saving Sight  10100 N Ambassador Drive Suite 200 Kansas City, Missouri 64153  a. PHONE 816-454-5454 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone b. Cartilage c. Cornea d. Dura Mater e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous f. Fascia g. Heart Valve h. Ligament i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous j. Pericardium k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic l. Sclera m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous n. Skin o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic p. Tendon q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic r. Vascular Graft																								
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<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 Antonio Bavuso, BS b. E-MAIL qa@saving-sight.org c. TITLE Executive Director d. DATE 16-NOV-2017																									

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Semen</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 colspan="13"> <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                 </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><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 colspan="13"> <input type="checkbox"/> Autologous  <input type="checkbox"/> Family Related  <input type="checkbox"/> Allogeneic                 </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><td></td></tr> <tr><td>q. 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<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Saving Sight Attn: Antonio Bavuso, BS 10100 N Ambassador Drive Suite 200 Kansas City, Missouri 64153  a. PHONE 816-454-5454 EXT 104																																																																																																																																																																																																																																																																																																																																																																																	
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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> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3001238378	<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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:16-NOV-2017 DISTRICT: Kansas City PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION							
<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>							
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Saving Sight  3506 Culpepper Circle, Suite D Springfield, Missouri 65804  a. PHONE 417-882-1532 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3003347229) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<b>Establishment Functions</b>			11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES			
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	Types of HCT / Ps	Recover	Screen	Test				
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Saving Sight Attn: Antonio J. Bavuso, BS 3506 S Culpepper Suite D Springfield, Missouri 65804  a. PHONE 816-454-5454 EXT 104	a. Bone b. Cartilage c. Cornea d. Dura Mater e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous f. Fascia g. Heart Valve h. Ligament i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous j. Pericardium k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic l. Sclera m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous n. Skin o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic p. Tendon q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic r. Vascular Graft	Package	Process	Store	Label	Distribute	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
<b>7. ENTER CORRECTIONS TO ITEM 6</b>	a. E-MAIL	s.	t.	u.	v.	b. PHONE	a. TYPED NAME Antonio J. Bavuso, BS b. E-MAIL qa@saving-sight.org c. TITLE Executive Director	d. DATE 16-NOV-2017

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> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3003153264	<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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:16-NOV-2017 DISTRICT: Kansas City PRINTED BY FDA:27-JAN-2018
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<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Saving Sight  404 Portland Street Columbia, Missouri 65201  a. PHONE 573-443-1471 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3003347229) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone b. Cartilage c. Cornea d. Dura Mater e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous f. Fascia g. Heart Valve h. Ligament i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous j. Pericardium k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic l. Sclera m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous n. Skin o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic p. Tendon q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic r. Vascular Graft																									
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