

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: 3001451641	<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:20-NOV-2017 DISTRICT: Chicago PRINTED BY FDA:27-JAN-2018
---	--	--	--

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 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 BIOLOGICAL DRUGS</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">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 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		
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																	
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Eversight  301 S. Prospect, Suite 2 Bloomington, Illinois 61704  a. PHONE 312-706-6770 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																								
<b>5. ENTER CORRECTIONS TO ITEM 4</b>																									
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Eversight Attn: Kevin W. Ross 4889 Venture Dr. Ann Arbor, Michigan 48108  a. PHONE 734-780-2100 EXT _____ b. PHONE _____																									
<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 Kevin W. Ross b. E-MAIL kwross@eversightvision.org c. TITLE President/CEO d. DATE 20-NOV-2017	s. t. u. v.																								

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: 3001451642	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:01-DEC-2017 DISTRICT: Chicago PRINTED BY FDA:27-JAN-2018
---	--	--	--

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 OFK 12/1/10</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> </table>	Types of HCT / Ps	Establishment Functions									11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	Recover	Screen	Test	Package	Process	Store	Label	Distribute	<b>14. PROPRIETARY NAME(S)</b>
Types of HCT / Ps	Establishment Functions									11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10	12. HCT/Ps REGULATED AS MEDICAL DEVICES				13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS								
	Recover	Screen	Test	Package	Process	Store	Label	Distribute															
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Eversight  547 West Jackson Blvd., Suite 600 Chicago, Illinois 60661  a. PHONE 312-706-6750 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																						
<b>5. ENTER CORRECTIONS TO ITEM 4</b>																							
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Eversight Attn: Kevin W. Ross 4889 Venture Dr. Ann Arbor, Michigan 48108  a. PHONE 734-780-2100 EXT _____ b. PHONE _____																							
<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 Kevin W. Ross b. E-MAIL kwross@eversightvision.org c. TITLE President / CEO d. DATE 30-NOV-2017	s. t. u. v.																						

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: 3002291793	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:01-DEC-2017 DISTRICT: New England PRINTED BY FDA:27-JAN-2018
---	--	--	---

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;"> <tr> <th rowspan="2" style="text-align: center;">Types of HCT / Ps</th> <th colspan="9" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">11. HCT/PS DESCRIBED IN 21 OFK 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="text-align: center;">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th style="text-align: center;">Recover</th> <th style="text-align: center;">Screen</th> <th style="text-align: center;">Test</th> <th style="text-align: center;">Package</th> <th style="text-align: center;">Process</th> <th style="text-align: center;">Store</th> <th style="text-align: center;">Label</th> <th style="text-align: center;">Distribute</th> </tr> </table>	Types of HCT / Ps	Establishment Functions									11. HCT/PS DESCRIBED IN 21 OFK 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												
Types of HCT / Ps	Establishment Functions									11. HCT/PS DESCRIBED IN 21 OFK 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																											
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Eversight  340 West Newberry Rd., Suite A Bloomfield, Connecticut 06002  a. PHONE 860-223-2020 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 Cell <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																																		
<b>5. ENTER CORRECTIONS TO ITEM 4</b>																																			
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Eversight Attn: Kevin W. Ross 4889 Venture Dr. Ann Arbor, Michigan 48108  a. PHONE 734-780-2100 EXT _____ b. PHONE _____																																			
<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 Kevin W. Ross b. E-MAIL kwross@eversightvision.org c. TITLE President/CEO d. DATE 30-NOV-2017	s.  t.  u.  v.																																		

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: 3002291793

2

**ADDITIONAL INFORMATION:**

Eversight relocation took place on 11.29.2017.

**Proprietary Name(s):**

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: 3013178553	<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 VALIDATED BY FDA:20-NOV-2017 DISTRICT: Int'l Operations Group PRINTED BY FDA:27-JAN-2018
---	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION	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)										
<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) Eversight Korea  Unit 202, 67, Gasan digital 2-ro Geumcheon-gu Seoul, 08588 Korea, Republic Of  a. PHONE +82-2-2088-7003 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<b>Establishment Functions</b>														
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute						
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Eversight Attn: Kevin W. Ross 4889 Venture Dr. Ann Arbor, Michigan 48108  a. PHONE 734-780-2100 EXT _____	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				X			X	X	X	X				
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____	s. t. u. v.														
<b>8. U.S. AGENT</b> Catherine M. McClory Eversight Michigan 4889 Venture Dr., Ann Arbor, Michigan 48108  a. E-MAIL cmccclory@eversightvision.org 734-887-2357	<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Kevin W. Ross b. E-MAIL kwross@eversightvision.org c. TITLE President/CEO d. DATE 20-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: 3000718321	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:01-DEC-2017 DISTRICT: Detroit PRINTED BY FDA:27-JAN-2018
---	--	--	--

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 OFK 121.10</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 OFK 121.10	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	
Types of HCT / Ps	Establishment Functions									11. HCT/Ps DESCRIBED IN 21 OFK 121.10	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																
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Eversight  4889 Venture Dr. Ann Arbor, Michigan 48108  a. PHONE 734-780-2100 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 <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 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 <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 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																							
<b>5. ENTER CORRECTIONS TO ITEM 4</b>																								
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Eversight Attn: Kevin W. Ross 4889 Venture Dr. Ann Arbor, Michigan 48108  a. PHONE 734-780-2100 EXT _____																								
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____																								
<b>8. U.S. AGENT</b>  a. E-MAIL _____																								
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Kevin W. Ross b. E-MAIL kwross@eversightvision.org c. TITLE President/CEO      d. DATE 30-NOV-2017	s. t. u. v.																							

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: 3001236615	<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:20-NOV-2017 DISTRICT: New Jersey PRINTED BY FDA:27-JAN-2018
---	--	--	---

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 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> <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 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		
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																	
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Eversight  77 Brant Avenue, Suite 100 Clark, New Jersey 07066  a. PHONE 732-382-3060 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																								
<b>5. ENTER CORRECTIONS TO ITEM 4</b>																									
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Eversight Attn: Kevin W. Ross 4889 Venture Drive Ann Arbor, Michigan 48108  a. PHONE 734-780-2100 EXT _____ b. PHONE _____																									
<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 Kevin W. Ross b. E-MAIL kwross@eversightvision.org c. TITLE President/CEO d. DATE 20-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: 3000718787	<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 VALIDATED BY FDA:20-NOV-2017 DISTRICT: Cincinnati PRINTED BY FDA:27-JAN-2018
---	--	--	--

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 OFK 121.10</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 OFK 121.10	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	
Types of HCT / Ps	Establishment Functions									11. HCT/Ps DESCRIBED IN 21 OFK 121.10	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																
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Eversight  6700 Euclid Ave., Suite 101 Cleveland, Ohio 44103  a. PHONE 216-706-4220 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 <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 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 <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 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																							
<b>5. ENTER CORRECTIONS TO ITEM 4</b>																								
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Eversight Attn: Kevin W. Ross, MPH 4889 Venture Dr. Ann Arbor, Michigan 48108  a. PHONE 734-780-2100 EXT _____																								
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____																								
<b>8. U.S. AGENT</b>  a. E-MAIL _____	s. t. u. v.																							
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Kevin W. Ross, MPH b. E-MAIL kwross@eversightvision.org c. TITLE President/CEO      d. DATE 20-NOV-2017																								