

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/TPs)**
 (See reverse side for instructions)

1. REGISTRATION NUMBER
 (FDA Establishment Number)
 FEI: 3010949709

2. REASON FOR SUBMISSION
 a. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2850 NO. _____
 b. DEVICES FDA 2881 NO. _____
 c. DRUG FDA 2856 NO. _____

4. PHYSICAL LOCATION (include legal name, number and street, city, state, county, and post office code)
 East Tennessee Lions Eye Bank
 201 W. Watauga Ave.
 Johnson City, Tennessee 37602

a. PHONE 865-305-9625 EXT _____
 b. SATELLITE RECOVERY ESTABLISHMENT
 (MANUFACTURING ESTABLISHMENT FEI NO. 3002689373)
 c. TESTING FOR MICRO-ORGANISMS ONLY

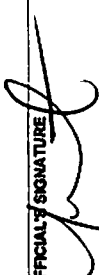
5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, county, and post office code)
 East Tennessee Lions Eye Bank
 Attn: Yvette Venters
 1924 Alcoa Hwy., Ste U-26
 Knoxville, Tennessee 37920

a. PHONE 865-305-9625 EXT _____
 b. PHONE _____


8. U.S. AGENT

a. E-MAIL _____
 b. TYPED NAME Yvette Venters
 c. E-MAIL yventers@utmck.edu
 d. DATE 17-NOV-2016

9. REPORTING OFFICIAL'S SIGNATURE


PART II - PRODUCT INFORMATION		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / P's				11. HCT/TPs DESCRIBED IN 21 CFR 1271.10		12. HCT/TPs REGULATED AS DRUGS OR BIOLOGICAL DRUGS		14. PROPRIETARY NAME(S)	
Types of HCT / P's		Recover	Screen	Test	Package	Process	Store	Label	Distribute		
a. Bone											
b. Cartilage											
c. Cornea		X								X	
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		X								X	
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											
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: 3002689373	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: 18-NOV-2016 DISTRICT: New Orleans PRINTED BY FDA: 15-DEC-2016
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PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2856 NO. _____ 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) East Tennessee Lions Eye Bank 1924 Alcoa Hwy., Ste U-26 Knoxville, Tennessee 37920 a. PHONE 865-305-9625 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY 6. 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) East Tennessee Lions Eye Bank Attn: Yvette Venters 1924 Alcoa Hwy., Ste U-26 Knoxville, Tennessee 37920 a. PHONE 865-305-9625 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ 8. U.S. AGENT a. E-MAIL _____ 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Yvette Venters b. E-MAIL yventers@utmck.edu c. TITLE QA Director d. DATE 17-NOV-2016	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">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2">11. HCT/Ps DESCRIBED IN 21 CFR 187.10</th> <th rowspan="2">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/Ps REGULATED AS BIOLOGICAL DRUGS</th> <th rowspan="2">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></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><td></td> </tr> <tr> <td>c. 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