

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION										1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 0001077605		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-2015 DISTRICT: New Orleans PRINTED BY FDA-03-DEC-2015								
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)																						
PART I - ESTABLISHMENT INFORMATION										PART II - PRODUCT INFORMATION												
3. OTHER FDA REGISTRATIONS										10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS												
a. BLOOD FDA 2830 NO. <u>FEI: 0001077605</u>										Types of HCT / PS												
b. DEVICES FDA 2891 NO. _____																						
c. DRUG FDA 2856 NO. _____										Establishment Functions												
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)																						
1601 Ailor Avenue Knoxville, Tennessee 37921 Medic Regional Blood Center										a. Bone	Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
b. PHONE 865-524-3074 EXT _____										b. Cartilage												
b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY										c. Cornea												
5. ENTER CORRECTIONS TO ITEM 4										d. Dura Mater												
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)										e. Embryo												
MEDIC Regional Blood Center Attn: Martha S. Cox, MPH, MT 1601 Ailor Avenue Knoxville, Tennessee 37921										f. Fascia												
a. PHONE 865-524-3074 EXT 668										g. Heart Valve												
7. ENTER CORRECTIONS TO ITEM 6										h. Ligament												
b. PHONE _____										i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
8. U.S. AGENT										j. Pericardium												
a. E-MAIL										k. Peripheral Blood Stem	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic											
9. REPORTING OFFICIAL'S SIGNATURE										l. Sclera	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
a. TYPED NAME Martha S. Cox, MPH, MT b. E-MAIL mcox@medicblood.org c. TITLE Chief Quality Officer										m. Semen	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
d. DATE 17-NOV-2015										n. Skin	<input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
										o. Somatic Cell Therapy Products												
										p. Tendon												
										q. Umbilical Cord Blood	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
										r. Vascular Graft												
										s. Therapeutic Cells												
										t. _____												
										u. _____												
										v. _____												