


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) <i>(See reverse side for instructions)</i>		1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3006042944	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 1 VALIDATED BY FDA:07-DEC-2009 DISTRICT: Dallas PRINTED BY FDA:18-DEC-2009																																																																																																																																																																																																																																																																																																																																																																																																																																	
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION			11. HCT/PS DESCRIBED IN 21 CFR 127.110 12. HCT/PS REGULATED AS MEDICAL DEVICES 13. HCT/PS REGULATED AS TISSUE OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																																																																																																																																																															
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS <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">Establishment Functions</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>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td></tr> <tr><td>b. Cartilage</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td></tr> <tr><td>c. Cornea</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</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></tr> <tr><td>e. 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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> RTI Donor Services - Texas 5489 Blair Road Dallas, Texas 75231 a. PHONE 214-443-9279 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		5. ENTER CORRECTIONS TO ITEM 4																																																																																																																																																																																																																																																																																																																																																																																																																																			
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> RTI Donor Services Attn: Beverly Bliss 11621 Research Circle Alachua, Florida 32616 a. PHONE 386-418-8888 EXT _____		7. ENTER CORRECTIONS TO ITEM 6			b. PHONE _____																																																																																																																																																																																																																																																																																																																																																																																																																																
8. U.S. AGENT a. E-MAIL _____		9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Beverly Bliss b. E-MAIL bbliss@rtix.com c. TITLE Vice President, RTI Donor Services d. DATE 04-DEC-2009																																																																																																																																																																																																																																																																																																																																																																																																																																			