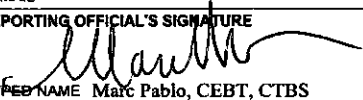


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for Instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3001503330	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: 02-DEC-2015 DISTRICT: Los Angeles PRINTED BY FDA: 16-DEC-2015																																																																																																																																																																																																																																																																																																																																																																																																	
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse; margin-top: 5px;"> <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 1271.10</th> <th rowspan="2">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/Ps DRUGS OR 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>X</td><td>X</td><td>X</td><td>X</td> <td></td><td></td><td>Autologous Bone</td> </tr> <tr> <td>b. Cartilage</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td> <td></td><td></td><td></td> </tr> <tr> <td>c. Cornea</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td> <td></td><td></td><td></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> <td></td><td></td><td></td> </tr> <tr> <td>e. Embryo</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></td> <td colspan="12"> <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous </td> </tr> <tr> <td>f. Fascia</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td> <td></td><td></td><td></td> </tr> <tr> <td>g. 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4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) California Transplant Services, Inc. dba SafetyGraft 5845 Owens Avenue Carlsbad, California 92008 a. PHONE 760-804-6890 EXT 101 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 (Include institution name if applicable, number and street, city, state, country, and post office code) California Transplant Services, Inc. dba SafetyGraft Attn: Marc Pablo, CEBT, CTBS PO Box 130815 Carlsbad, California 92013 a. PHONE 760-804-6890 EXT 101																																																																																																																																																																																																																																																																																																																																																																																																
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9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Marc Pablo, CEBT, CTBS b. E-MAIL mpablo@catransplant.org c. TITLE Sr. Vice President d. DATE 01-DEC-2015																																																																																																																																																																																																																																																																																																																																																																																																				