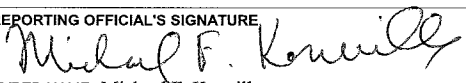


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) <i>(See reverse side for instructions)</i>		1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 1000122198		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:14-DEC-2011 DISTRICT: Philadelphia PRINTED BY FDA:15-DEC-2011																																																																																																																																																																																																																								
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)																																																																																																																																																																																																																			
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. FEI: 0002247110		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps																																																																																																																																																																																																																												
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> WuXi AppTec Inc. 4751 League Island Blvd. (Contract Manufacturing) Philadelphia, Pennsylvania 19112 a. PHONE 215-218-5500 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<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></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></tr> <tr><td>c. Cornea</td><td></td><td></td><td></td><td></td><td></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></tr> <tr><td>e. Embryo</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>f. Fascia</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>g. Heart Valve</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>h. Ligament</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>i. Oocyte</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>j. Pericardium</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>k. Peripheral Blood Stem Cells</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>l. Sclera</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>m. Semen</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>n. Skin</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>o. Somatic Cell Therapy Products</td><td></td><td></td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr> <tr><td>p. Tendon</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>q. Umbilical Cord Blood Stem Cells</td><td></td><td></td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr> <tr><td>r. Vascular Graft</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>s. Amniotic Membrane</td><td></td><td></td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr> <tr><td>t.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>u.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>v.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>						Types of HCT / Ps	Establishment Functions								Recover	Screen	Test	Package	Process	Store	Label	Distribute	a. Bone									b. Cartilage									c. Cornea									d. Dura Mater									e. Embryo									f. Fascia									g. Heart Valve									h. Ligament									i. Oocyte									j. Pericardium									k. Peripheral Blood Stem Cells									l. Sclera									m. Semen									n. Skin									o. Somatic Cell Therapy Products				X	X	X	X	X	p. Tendon									q. Umbilical Cord Blood Stem Cells				X	X	X	X	X	r. Vascular Graft									s. Amniotic Membrane				X	X	X	X	X	t.									u.									v.								
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9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Michael F. Kenville b. E-MAIL michael.kenville@WuXiAppTec.com c. TITLE Site Director, Quality Assurance d. DATE 13-DEC-2011											NuCel																																																																																																																																																																																																																			