

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION  <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier):  FEI: 3003435372	<b>2. REASON FOR SUBMISSION</b> 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   <b>* 3003435372 *</b>  VALIDATED BY FDA: 22-FEB-2007 PRINTED BY FDA: 02-MAR-2007 DISTRICT OFFICE: New England
---	---	--	--

<b>PART I - ESTABLISHMENT INFORMATION</b>	<b>PART II - PRODUCT INFORMATION</b>
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS:</b> a. <input type="checkbox"/> RECOVER    c. <input checked="" type="checkbox"/> TEST    e. <input type="checkbox"/> PROCESS    g. <input type="checkbox"/> LABEL b. <input type="checkbox"/> SCREEN    d. <input type="checkbox"/> PACKAGE    f. <input checked="" type="checkbox"/> STORE    h. <input type="checkbox"/> DISTRIBUTE

<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i>	<b>11.</b>	<b>12.</b>	<b>13.</b>
New England Medical Center Clinical Laboratory 750 Washington Street Boston, Massachusetts 02111  PHONE 617-636-5000                      EXT	<b>TYPES OF HCT/PS</b>  HCT/PS DESCRIBED IN 21 CFR 1271.10	HCT/PS REGULATED AS MEDICAL DEVICES, DRUGS, OR BIOLOGICAL DRUGS	PROPRIETARY NAME(S)
	a. Bone	X	
	b. Cartilage	X	
	c. Cornea	X	
	d. Dura Mater		

<b>5. ENTER CORRECTIONS TO ITEM 4</b>	e. Embryo	X	
	f. Fascia	X	
	g. Heart Valve	X	

<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i>	h. Ligament	X	
New England Medical Center Attn: Eleanor A. Kern 750 Washington Street, Box 830 Boston, Massachusetts 02111  PHONE 617-636-5822                      EXT	i. Oocyte		
	j. Pericardium	X	
	k. Peripheral Blood Stem Cells		
	l. Sclera		

<b>7. ENTER CORRECTIONS TO ITEM 6</b>	m. Semen	X	
	n. Skin	X	
	o. Somatic Cells		

<b>8. U.S. AGENT</b>	p. Tendon	X	
a. E-MAIL    b. PHONE	q. Umbilical Cord Blood Stem Cells		
	r. Vascular Graft	X	

<b>9. REPORTING OFFICIAL'S SIGNATURE</b>	s.		
a. TYPED NAME Eleanor A. Kern b. E-MAIL ekern@tufts-nemc.org c. TITLE Lab Supervisor    d. DATE 12-DEC-2006	t.		
	u.		
	v.		