

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
 (Field Establishment Identifier)
 FEI: 0002246948

2. REASON FOR SUBMISSION
 a. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

See Instructions for OMB Statement
 FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14
 VALIDATION--FOR FDA USE ONLY
 VALIDATED BY FDA:01-DEC-2011
 DISTRICT: Florida
 PRINTED BY FDA:02-DEC-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. FEI: 0002246948
 b. DEVICES FDA 2891 NO. _____
 c. DRUG FDA 2656 NO. _____


4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)
 Cryo-Cell International, Inc.
 700 Brooker Creek Boulevard
 Suite 1800
 Oldsmar, Florida 34677

5. ENTER CORRECTIONS TO ITEM 4
 a. PHONE 813-749-2100 EXT _____
 b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)
 c. TESTING FOR MICRO-ORGANISMS ONLY

6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code)
 Cryo-Cell International, Inc.
 Attn: Davor Milosevic
 700 Brooker Creek Boulevard
 Suite 1800
 Oldsmar, Florida 34677

7. ENTER CORRECTIONS TO ITEM 6
 a. PHONE 813-749-2116 EXT _____
 b. PHONE _____

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE

 a. TYPED NAME Davor Milosevic
 b. E-MAIL dmilosevic@cryo-cell.com
 c. TITLE Regulatory Specialist
 d. DATE 30-NOV-2011

PART II - PRODUCT INFORMATION

Types of HCT / Ps	Establishment Functions						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)
	Recover	Screen	Test	Package	Process	Store				
a. Bone										
b. Cartilage										
c. Cornea										
d. Dura Mater										
e. Embryo	<input checked="" type="checkbox"/> SIP	<input checked="" type="checkbox"/> Directed	<input type="checkbox"/> Anonymous			X		X	X	
f. Fascia										
g. Heart Valve										
h. Ligament										
i. Oocyte	<input checked="" type="checkbox"/> SIP	<input checked="" type="checkbox"/> Directed	<input type="checkbox"/> Anonymous			X		X	X	
j. Pericardium										
k. Peripheral Blood Stem Cells	<input type="checkbox"/> Autologous	<input type="checkbox"/> Family Related	<input type="checkbox"/> Allogeneic							
l. Sclera										
m. Semen	<input checked="" type="checkbox"/> SIP	<input checked="" type="checkbox"/> Directed	<input type="checkbox"/> Anonymous			X		X	X	
n. Skin										
o. Somatic Cell Therapy Products	<input type="checkbox"/> Autologous	<input type="checkbox"/> Family Related	<input type="checkbox"/> Allogeneic							
p. Tendon										
q. Umbilical Cord Blood Stem Cells	<input checked="" type="checkbox"/> Autologous	<input checked="" type="checkbox"/> Family Related	<input type="checkbox"/> Allogeneic			X		X	X	
r. Vascular Graft										
s. Menstrual Blood		X				X		X	X	
t.										
u.										
v.										C-cell

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ADDITIONAL INFORMATION:
Cryopreservation of Umbilical Cord Tissue to include: screening,
packaging, storing, and labeling of the tissue.

Proprietary Name(s):