See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 0002246948

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:19-NOV-2015
DISTRICT: Florida
PRINTED BY FDA:03-DEC-2015

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

a. PHONE 813-749-2100 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.
c. ☐ 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)
Cryo-Cell International, Inc.
Attn: Andrea L. Darrow
700 Brooker Creek Boulevard
Suite 1800
Oldsmar, Florida 34677

a. PHONE 813-749-2188 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE
Andrea L Darrow
a. TYPED NAME Andrea L. Darrow
b. E-MAIL adarrow@cryo-cell.com
c. TITLE QA Manager d. DATE 18-NOV-2015

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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

FORM FDA - 3356 (5/14)