

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)
FEI: 0001270007

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

VALIDATION—FOR FDA USE ONLY
VALIDATED BY FDA: 30-NOV-2017
DISTRICT: New England
PRINTED BY FDA: 27-JAN-2018

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)

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
a. Bone								
b. Cartilage								
c. Cornea		X						
d. Dura Mater								
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous								
f. Fascia								
g. Heart Valve								
h. Ligament								
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous								
j. Pericardium								
k. Peripheral Blood Stem Cell <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X	X	X	X	X	X	X
l. Sclera								
m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input type="checkbox"/> Anonymous		X						X
n. Skin								
o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X			X			X	
p. Tendon								
q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic		X						X
r. Vascular Graft								
s. Therapeutic Cells	X	X	X	X	X	X	X	X
t.								
u.								
v.								

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. FEI: 0001270007
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2855 NO

4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)

Rhode Island Blood Center
405 Promenade Street
Providence, Rhode Island 02908

a. PHONE 401-453-8364 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)

Rhode Island Blood Center
Attn: Carolyn T. Young, MD
405 Promenade Street
Providence, Rhode Island 02908

a. PHONE 401-453-8392 EXT
b. PHONE

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE

Carolyn T. Young, M.D.
a. TYPED NAME Carolyn T. Young, MD
b. E-MAIL cyoung@ribc.org
c. TITLE VP and CMO
d. DATE 30-NOV-2017