

1. REGISTRATION NUMBER
 (FDA Establishment Identifier)
 FEI: 3000215348

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: 17-NOV-2016
 DISTRICT: Denver
 PRINTED BY FDA: 15-DEC-2016

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. _____

c. DRUG FDA 2666 NO. _____

4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)
 Rocky Mountain Tissue Bank
 2993 S. Peoria St., #390
 Aurora, Colorado 80014

a. PHONE 303-337-3330 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)
 Rocky Mountain Tissue Bank
 Attn: Deborah M. Spillman, CTBS
 2993 S. Peoria St., #390
 Aurora, Colorado 80014


a. PHONE 303-337-3330 EXT _____

7. ENTER CORRECTIONS TO ITEM 6

b. PHONE _____

8. U.S. AGENT

a. E-MAIL _____

3. REPORTING OFFICER'S SIGNATURE


a. TYPED NAME Deborah M. Spillman, CTBS

b. E-MAIL DebSpill@aol.com

c. TITLE President

d. DATE 16-NOV-2016

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND 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 NAMES
	Types of HCT / Ps	Recover	Screen	Test	Package	Process				
a. Bone					X	X	X	X	X	
b. Cartilage										
c. Cornea										
d. Dura Mater										
e. Embryo										
f. Fascia										
g. Heart Valve										
h. Ligament										
i. Oocyte										
j. Pericardium										
k. Peripheral Blood Stem										
l. Sclera										
m. Semen										
n. Skin										
o. Somatic Cell Therapy Products										
p. Tendon										
q. Umbilical Cord Blood										
r. Vascular Graft										
s.										
t.										
u.										
v.										