

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: 1000517466

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: 16-NOV-2017
 DISTRICT: Denver
 PRINTED BY FDA: 27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. _____
 b. DEVICES FDA 2891 NO. _____
 c. DRUG FDA 2856 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, county, and post office code)
 Rocky Mountain Lions Eye Bank
 1675 Aurora Court
 E12049
 Aurora, Colorado 80045

a. PHONE 720-848-3937 EXT _____
 b. SATELLITE RECOVERY ESTABLISHMENT
 MANUFACTURING ESTABLISHMENT FEI NO. _____
 TESTING FOR MICRO-ORGANISMS ONLY
 c. ENTER CORRECTIONS TO ITEM 4 _____

5. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, county, and post office code)
 Rocky Mountain Lions Eye Bank
 Attn: Jaime Wasniewski
 Mail Stop F751
 1675 Aurora Court
 Aurora, Colorado 80045

a. PHONE 720-848-3934 EXT _____
 b. PHONE _____
 7. ENTER CORRECTIONS TO ITEM 6 _____

8. U.S. AGENT

a. E-MAIL
 Jaime Wasniewski
 a. REPORTING OFFICIAL'S SIGNATURE
 a. TYPED NAME Jaime Wasniewski
 b. E-MAIL jwasniewski@comcas.org
 c. TITLE Quality Assurance Manager
 d. DATE 16-NOV-2017

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 DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process				
a. Bone									
b. Cartilage									
c. Cornea	X	X		X	X	X	X	X	X
d. Dura Mater									
e. Embryo									
f. Falcia									
g. Heart Valve									
h. Ligament									
i. Oocyte									
j. Pericardium									
k. Peripheral Blood Stem									
l. Sclera	X	X		X	X	X	X	X	X
m. Semen									
n. Skin									
o. Somatic Cell Therapy Products									
p. Tendon									
q. Umbilical Cord Blood									
r. Vascular Graft									
s.									
t.									
u.									
v.									

