

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: 3006040855

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-2017
DISTRICT Seattle
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: _____

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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	Store	Label	Distribute					
a. Bone													
b. Cartilage													
c. Cornea	X	X	X	X	X	X	X	X	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 <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
l. Sclera	X	X	X	X	X	X	X	X	X				
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
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 <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
r. Vascular Graft													
s.													
t.													
u.													
v.													

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

Idaho Lions Sight and Hearing Foundation db Idaho Lions Eye Bank

1090 N. Cole Road
Boise, Idaho 83704

- a. PHONE 208-338-5466 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)

Idaho Lions Eye Bank
Attn: Edwin Marshall, CEPT
1090 N. Cole Road
Boise, Idaho 83704

- a. PHONE 208-338-5466 EXT _____
- b. PHONE _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

- a. TYPED NAME Edwin Marshall, CEPT
- b. E-MAIL edwin@idaholions.org
- c. TITLE Technical Director

d. DATE 16-NOV-2017