

**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, country, and post office code)

Lions Eye Bank of New Jersey  
77 Brant Avenue, Suite 100  
Clark, New Jersey 07066

5. ENTER CORRECTIONS TO ITEM 4

a. PHONE 732-382-3060 EXT \_\_\_\_\_

b.  SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. \_\_\_\_\_)

c.  TESTING FOR MICRO-ORGANISMS ONLY

6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code)

Midwest Eye-Banks  
Attn: Kevin W. Ross  
4889 Venture Drive  
Ann Arbor, Michigan 48108

7. ENTER CORRECTIONS TO ITEM 6

a. PHONE 734-780-2100 EXT \_\_\_\_\_

b. PHONE \_\_\_\_\_

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Kevin W. Ross  
b. E-MAIL kwross@midwesteyebanks.org  
c. TITLE President/CEO  
d. DATE 18-NOV-2010

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