See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,

FEI: 3011697159

1. REGISTRATION NUMBER (FDA Establishment Identifier)

2. REASON FOR SUBMISSION a. INITIAL REGISTRATION / LISTING VALIDATED BY FDA:06-JAN-2016 b. X ANNUAL REGISTRATION / LISTING DISTRICT: New York PRINTED BY FDA:22-JAN-2016

VALIDATION--FOR FDA USE ONLY

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps (See reverse side for instructions)	5)							c. CHANGE IN INFORMATION d. INACTIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION											돌유12	무무유:3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISI	HMENT FUNCTION	NS AND	TYPES	OF HC	T / Ps					RSS T	SEE	P S S S S S S S S S S S S S S S S S S S	
a. BLOOD FDA 2830 NO			Establishment Functions						11. HCT/Ps DESCRIBED I CFR 1271.10	F A PE	E SEE	14. PROPRIETARY NAME(S)		
b. DEVICES FDA 2891 NO	Types of HCT / Ps		Recover	Screen	Screen Test Packa	Package	Process Store	Store	Label	Distribute	Z	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	(-7
c. DRUG FDA 2656 NO													0,	
PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Sight Society of NENY, Inc	a. Bone													
	b. Cartilage													
Lions Eye Bank of Rochester 100 Corporate Woods	c. Cornea		X	X	X	X		X	X	X	X			
Suite 130 Rochester, New York 14623 a. PHONE 587-272-7890 EXT	d. Dura Mater													
	e. Embryo	SIP Directed Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3000718056 c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia													
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve													
	h. Ligament													
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Sight Society of NENY, Inc Attn: Victoria Alder, RN, BSN, CEBT Lions Eye Bank of Rochester 6 Executive Park Drive Albany, New York 12203	i. Oocyte	SIP Directed Anonymous												
	j. Pericardium													
	k. Peripheral Blood Stem	Autologous Family Related Allogeneic												
	I. Sclera							X		X	X			
a. PHONE 585-753-5905 EXT	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin													
	o. Somatic Cell Therapy Products	Autologous Family Related Allogeneic												
8. U.S. AGENT	p. Tendon													
	q. Umbilical Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft													
9. REPORTING OFFICIAL'S SIGNATURE	S.													
a. TYPED NAME Victoria Alder, RN, BSN, CEBT	t.													
b. E-MAIL vadler@lionseyebankalbany.org	u.													
c. TITLE Executive Director d. DATE 11-DEC-2015	V.													