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,

1. REGISTRATION NUMBER	2. REASON FOR SUBMISSION
(FDA Establishment Identifier)	a. INITIAL REGISTRATION / LISTIN
FEI: 3000718320	b. X ANNUAL REGISTRATION / LIST
	CHANCE IN INFORMATION

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:19-NOV-2016 TING DISTRICT: Detroit
PRINTED BY FDA:15-DEC-2016

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps (See reverse side for instructions)								c. CHANGE IN INFORMATION d. INACTIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION										Ω <u>π</u> .±	돌유12	무무유3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												이 이 이 이 이 이 이 이 이 이 이 이 이 이 이 이 이 이 이	
a. BLOOD FDA 2830 NO.	Establishment Functions										71.10	FAS	SCA E'S	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		Types of HCT / Ps Recover	Recover Screen Test	Package P	Process	Store	Label	Distribute	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	HAME(O)	
c. DRUG FDA 2656 NO													o	
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 	a. Bone													
Indiana Lions Eye Bank	b. Cartilage													
727 E. 86th Street Indianapolis, Indiana 46240 a. PHONE 317-808-5000 EXT	c. Cornea		X	X		X	X	X	X	X	X			
	d. Dura Mater													
	e. Embryo	SIP Directed Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 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) Indiana Lions Eye Bank Attn: Kara B. Johnston 727 E. 86th Street Indianapolis, Indiana 46240	i. Oocyte	SIP Directed Anonymous												
	j. Pericardium													
	k. Peripheral Blood Stem	Autologous Family Related Allogeneic												
	I. Sclera		X	X		X	X	X	X	X	X			
a. PHONE 317-808-5008 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.													
	t.													
a. TYPED NAME Kara B. Johnston b. E-MAIL kjohnston@ilettb.org	u.													
c. TITLE Manager, Quality Systems d. DATE 18-NOV-2016	v.													