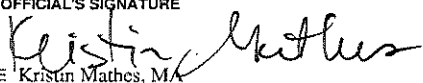


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3013534653	2. REASON FOR SUBMISSION a. <input checked="" type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:25-MAY-2017 DISTRICT: New England PRINTED BY FDA:25-MAY-2017																																																																																																																																																																																																																										
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION						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)																																																																																																																																																																																																																			
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps																																																																																																																																																																																																																												
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lions VisionGift 27-43 Wormwood Street Suite 100 Boston, Massachusetts 02210 a. PHONE 5038087026 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr> <td>a. Bone</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>b. Cartilage</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>c. 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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) Lions VisionGift Attn: Kristin Mathes, MA 2201 SE 11th Ave Suite 100 Portland, Oregon 97214 a. PHONE 503-808-7026 EXT _____ b. PHONE _____																																																																																																																																																																																																																												
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9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Kristin Mathes, MA b. E-MAIL kristin@visiongift.org c. TITLE Chief Quality and Regulatory Officer d. DATE 23-JAN-2017																																																																																																																																																																																																																														

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(See reverse side for Instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)
FEI: 3013534653

ADDITIONAL INFORMATION:

Lions VisionGift in Boston, MA is a processing branch of Lions
VisionGift in Portland, OR. Manufacturing is expected to start by
May 2017.

Proprietary Name(s):