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 **DESCRIBED IN 21 CFR 1271.10**

FEI: 1000025033

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/19/2024 Summary Report Print Date: 12/20/2024

Legal Name and Location:

Florida Lions Eye Bank 900 NW 17th Street #348

Ext.:

Miami, Florida 33136 USA

Phone: 305-326-6359

Reporting Official:

Elizabeth Fout, Executive Director

PO Box 016880 Miami, Florida 33101

Phone: 305-482-4323 Ext. Efcaraza@med.miami.edu

Satellite Recovery Establishment:

No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

| | | Establishment Functions | | | | | | | | | | |
|-------------------------------------|---------------|-------------------------|--------|---------------|---------|---------|-------|-------|------------|------------------------|-----------------------|---------------------|
| HCT/P(s) | Donor Type(s) | Recover | Screen | Donor Testing | Package | Process | Store | Label | Distribute | Date of Discontinuance | Date of Resumption | Proprietary Name(s) |
| | | | | | | | | | | | | |
| Amniotic Membrane | | | | | | | | | | | | |
| Blood Vessel | | | | | | | | | | | | |
| Bone | | | | | | | | | | | | |
| Cardiac Tissue - non-valved | | | | | | | | | | | | |
| Cartilage | | | | | | | | | | | | |
| Cornea | | х | Х | | X | X | Х | Х | X | | | |
| Dura Mater | | | | | | | | | | | | |
| Embryo | | | | | | | | | | | | |
| Fascia | | | | | | | | | | | | |
| Heart Valve | | | | | | | | | | | | |
| HPC Apheresis | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | |
| Ligament | | | | | | | | | | | | |
| Nerve Tissue | | | | | | | | | | | | |
| Oocyte | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | |
| Pericardium | | | | | | | | | | | | |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | |
| Sclera | | х | Х | | Х | Х | Х | Х | Х | | | |
| Semen | | | | | | | | | | | | |
| Skin | | | | | | | | | | | | |
| Tendon | | | | | | | | | | | | |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | | | | | | | | |

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 1000025033 Legal Name: Florida Lions Eye Bank