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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br><b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,<br/>         TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS<br/>         DESCRIBED IN 21 CFR 1271.10</b> | <b>FEI:</b> 3000718792 | <b>Other FDA Registrations:</b><br><b>Blood:</b><br><b>Devices:</b><br><b>Drugs:</b> | Reason For Last Submission: Annual Registration/Listing<br>Last Annual Registration Year: 2025<br>Last Registration Receipt Date: 11/15/2024<br>Summary Report Print Date: 12/05/2024 |
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| <b>Legal Name and Location:</b><br><br>KLEB, Inc<br>1510 Newtown Pike<br>Suite 140<br><br>Lexington, Kentucky 40511<br>USA<br><br>Phone: 859-368-0957 <b>Ext.:</b> | <b>Reporting Official:</b><br><br>Brooke Hutcheson, QA/RA Coordinator<br>10160 Linn Station Road<br>Louisville, Kentucky 40223<br>USA<br>Phone: 502-290-5330 Ext.<br>bhutcheson@ebky.org | <b>Satellite Recovery Establishment:</b> No<br><b>Parent Manufacturing Establishment FEI No.:</b><br><b>Testing For Micro-Organisms Only:</b> No<br><br>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)). |
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| HCT/P(s)                            | Donor Type(s) | Establishment Functions |        |               |         |         |       |       |            | Date of Discontinuance | Date of Resumption | Proprietary Name(s) |
|-------------------------------------|---------------|-------------------------|--------|---------------|---------|---------|-------|-------|------------|------------------------|--------------------|---------------------|
|                                     |               | Recover                 | Screen | Donor Testing | Package | Process | Store | Label | Distribute |                        |                    |                     |
| Amniotic Membrane                   |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Blood Vessel                        |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Bone                                |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cardiac Tissue - non-valved         |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cartilage                           |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cornea                              |               | X                       | X      |               | X       |         | X     | X     | 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                              |               | X                       | X      |               | X       |         | X     | X     | X          |                        |                    |                     |
| Semen                               |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Skin                                |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Tendon                              |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Testicular Tissue                   |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Tooth Pulp                          |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Umbilical Cord Tissue               |               |                         |        |               |         |         |       |       |            |                        |                    |                     |

**Additional Information:** Preparation of autologous serum eye drops.

**Proprietary Name(s):**

FEI: 3000718792

Legal Name:

KLEB, Inc