## 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**

Ext.:

FEI: 0002170665

Other FDA Registrations: Blood: FEI: 0002170665

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/16/2023 Summary Report Print Date: 12/01/2023

Legal Name and Location:

Innovative Blood Resources, a Division of New York Blood Center, Inc.

737 Pelham Boulevard

Jed B Gorlin. Medical Director 737 Pelham Boulevard St. Paul, Minnesota 55114

Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only:

Satellite Recovery Establishment:

No

No

St. Paul, Minnesota 55114

USA

Phone: 651-332-7000

Phone: 651-332-7284 Ext. Jed.GorlinMD@innovativeblood.org

Reporting Official:

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)).

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

FEI:

| Additional Information: | No additional information provided |
|-------------------------|------------------------------------|

Proprietary Name(s):

FEI: 0002170665 Legal Name: Innovative Blood Resources, a Division of New York Blood Center, Inc.