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| 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: 1000592496 | Other FDA Registrations: Blood: Devices: FEI: 0001060818 Drugs: | Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/07/2023 Summary Report Print Date: 12/15/2023 |
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| Legal Name and Location: BioHorizons Implant Systems Inc. 2300 Riverchase Center Birmingham, Alabama 35244 USA Phone: 205-967-7880 Ext.: N/A | Reporting Official: Jared O Cooper, Director, Regulatory Affairs 2300 Riverchase Center Birmingham, Alabama 35244 USA Phone: 205-967-7880 Ext. 7994 jcooper@biohorizons.com | 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)). |
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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 | | | | | | | X | | X | | | Mem-lok Amnio |
| Blood Vessel | | | | | | | | | | | | |
| Bone | | | | | | | X | | X | | | MinerOss, Grafton, Genate |
| Cardiac Tissue - non-valved | | | | | | | | | | | | |
| Cartilage | | | | | | | | | | | | |
| Cornea | | | | | | | | | | | | |
| Dura Mater | | | | | | | | | | | | |
| Embryo | | | | | | | | | | | | |
| Fascia | | | | | | | | | | | | |
| Heart Valve | | | | | | | | | | | | |
| HPC Apheresis | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | |
| Ligament | | | | | | | | | | | | |
| Nerve Tissue | | | | | | | | | | | | |
| Oocyte | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | |
| Pericardium | | | | | | | X | | X | | | Mem-Lok Pericardium |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | |
| Sclera | | | | | | | | | | | | |
| Semen | | | | | | | | | | | | |
| Skin | | | | | | | X | | X | | | ***See full text on next page. |
| Tendon | | | | | | | | | | | | |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | | | | | | | | |

Additional Information: No additional information provided.

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| Proprietary Name(s): | Skin | AlloDerm Select, AlloDerm Select GBR |
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FEI:1000592496

Legal Name:BioHorizons Implant Systems Inc.