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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> 3011545418 | <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: 2022<br>Last Registration Receipt Date: 12/13/2021<br>Summary Report Print Date: 12/15/2021 |
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| <b>Legal Name and Location:</b><br><br>Amnio Technology, LLC<br>22510 N 18th Drive<br><br>Phoenix, Arizona 85027<br>USA<br><br>Phone: 888-232-8550 <b>Ext.:</b> | <b>Reporting Official:</b><br>Tiana Golding, Associate Director Regulatory Affairs<br>22510 N 18th Drive<br>Phoenix, Arizona 85027<br>USA<br>Phone: 623-344-1761 Ext.<br>tgolding@amniotechnology.com | <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                   |               |                         |        |               |         |         |       | X     |            |                        | X                  |                     | continues on next page |
| Blood Vessel                        |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Bone                                |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| 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                         |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Peripheral Blood Mononuclear Cells  |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Peritoneal Membrane                 |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Sclera                              |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Semen                               |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Skin                                |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Tendon                              |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Testicular Tissue                   |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Tooth Pulp                          |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |
| Umbilical Cord Tissue               |               |                         |        |               |         |         |       |       |            |                        |                    |                     |                        |

**Additional Information:**

Amniotic Membrane:  
PalinGen Membrane  
PalinGen Hydromembrane  
PalinGen XPlus Membrane  
PalinGen XPlus Hydromembrane  
KardiaMembrane  
SXBarrier  
SXBarrier-Wet  
ASGBarrier  
ASGBarrier-Wet  
SuiGen Membrane  
SuiGen Hydromembrane  
SuiGen XPlus Membrane  
SuiGen XPlus Hydromembrane  
STRATOGEN Membrane  
STRATOGEN Plus Membrane  
PalinGen Dual Layer Membrane  
PalinGen Dual Layer X-Membrane  
Zenith Graft Membrane  
Axolotl Biologix Single Layer Graft  
Axolotl Biologix Dual Layer Graft  
AlonShield Dc.02/17  
AlonShield-Wet Dc.02/17  
Nanofactor Membrane Dc.12/16  
AlloShield Dc.05/15  
AlloShield Dry Dc.05/15  
XWRAP ECM Dc.01/15  
XWRAP HYDRO Dc.01/15  
XWRAP DRY Dc.01/15  
XWRAP HYDRO PLUS Dc.01/15

**Proprietary Name(s):**

FEI: 3011545418

Legal Name:

Amnio Technology, LLC