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 (HCT/Ps)

(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 3011545418

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☐ ANNUAL REGISTRATION / LISTING
c. ☒ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:01-JUL-2017
DISTRICT: Los Angeles
PRINTED BY FDA:28-AUG-2017

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. _____

c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)

Amnio Technology, LLC

22510 N 18th Drive
Phoenix, Arizona 85027

a. PHONE 888-232-8550 EXT

b. ☐ SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO._____

c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

Amnio Technology, LLC
Attn: Grant D. Senner, MD
22510 N 18th Drive
Phoenix, Arizona 85027

a. PHONE 888-232-8550 EXT 102

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Grant D. Senner, MD

b. E-MAIL gsenner@amniotechnology.com

c. TITLE CEO d. DATE 30-JUN-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium												
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin												
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon												
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft												
s. Amniotic Membrane						X		X	X			s). continues on next page
t. Amniotic Fluid								X	X			t). continues on next page
u.												
v.												

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ADDITIONAL INFORMATION:

Proprietary Name(s):

s.
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
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
t.
PalinGen Flow
PalinGen SportFlow
PalinGen InovoFlo
ProMatrX ACF
KardiaFlow
ASGFluid
AlonLiquid
Amnio Biologix Dc.03/17
cell-ECT
Gryphon Amnio Flow
SXFluid
SXMatrix
AmnioFlex
SuiGen MatrX
SuiGen Flow
STRATOGEN Flow
Nanofactor Flow Dc.12/16
Nanofactor SportFlow Dc.12/16
AlloGen Dc.05/15
AlloGenLI Dc.05/15
FloGraft Dc.01/15
FloGraft FREEDOM Dc.01/15
AllOPUR Dc.11/13