See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 3005897621

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:17-MAR-2017
DISTRICT: Atlanta
PRINTED BY FDA:17-MAR-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)

MiMedx Tissue Services, LLC

1775 West Oak Commons Court NE
Marietta, Georgia 30062

a. PHONE 770-651-9254 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)

MiMedx Tissue Services, LLC
Attn: Mark Rogers
1775 West Oak Commons Ct NE
Marietta, Georgia 30062

a. PHONE 770-651-9254 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Mark Rogers

b. E-MAIL mrogers@mimedx.com

c. TITLE VP, QA/RA d. DATE 16-MAR-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		X							X			
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		X							X			
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	X	X	X	X	X			*** See full text on next page
t. Placenta	X	X		X	X	X	X	X	X			*** See full text on next page
u. Amniotic Fluid		X		X	X	X	X	X	X			*** See full text on next page
v. Umbilical Cord	X	X		X	X	X	X	X	X			*** See full text on next page

FORM FDA - 3356 (5/14)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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ADDITIONAL INFORMATION:

Proprietary Names:
s. Amniotic Membrane: AmbioDisk, Ambio2, Ambio5, AmnioFix, AmnioRepair, AmnioShield, AmnioVantage, AmnioVo, BioXclude, EpiBurn, EpiFix, EpiXL, RDX2, OcuFix1, OcuFix2, Provenda
t. Placenta: AmnioFill
u. Umbilical Cord:AmnioCord, AmnioVantage, EpiCord, Provenda
v. Amniotic Fluid: AmnioFlo, AmnioVantage, OrthoFlo

Proprietary Name(s):

April 12, 2017

To Whom It May Concern,

In regards to Form FDA 3356, the expiration date listed in the top corner (OMB No. 0910-0543) corresponds to an internal form expiration/review date that is for FDA Use Only. This date does not correspond with the expiration of a facility's registration with the FDA.

Despite the form's expiration date of 03/31/2017, MiMedx Tissue Services, LLC maintains a Registered/Active status with the FDA as a Tissue Bank (Registration Number 3005897621) and will continue to maintain this registration per FDA requirements.

The MiMedx registration is valid for one year post the FDA's validation date of 03/17/2017. Therefore, the posted FDA registration is valid through 03/17/2018.

Any additional registration inquiries may be made by contacting MiMedx Customer Service at CustomerService@MiMedx.com or 866-477-4219.

Thank you,

J. Mark Rogers, CTBS
VP, QA/RA
Tissue Bank Director Designee