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: 3003410694

2. REASON FOR SUBMISSION

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

VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA:27-MAY-2017
DISTRICT: New Orleans
PRINTED BY FDA:22-JUN-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)

Prime Merger Sub, LLC (dba NuTech Medical) a Division of Organogenesis, Inc.))
2641 Rocky Ridge Lane
Birmingham, Alabama 35216

a. PHONE 205-290-2158 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)

Prime Merger Sub, LLC (dba NuTech Medical) a Division of Organogenesis, Inc))
Attn: Rita K. Cain, CTBS
PO Box 36639
Birmingham, Alabama 35236

a. PHONE 205-329-7267 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Rita K. Cain, CTBS
b. E-MAIL rcain@organo.com
c. TITLE Quality Director d. DATE 26-MAY-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	X	X		FiberOS, OCM + DBM, OsteoIN DBM
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	X	X	X			**NuCel, NuShield, Affinity, ReNu**
t. Amniotic Fluid				X	X	X	X	X	X			**NuCel , ReNu**
u.												
v.												

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ADDITIONAL INFORMATION:

Prime Merger Sub, LLC (dba NuTech Medical) a Division of Organogenesis, Inc. is contracted with WuXi AppTec, Inc. for Packaging, Processing and Labeling.

Proprietary Name(s):