See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 6/30/2020

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: 3008865245

2. REASON FOR SUBMISSION
- a. [ ] INITIAL REGISTRATION / LISTING
- b. [X] ANNUAL REGISTRATION / LISTING
- c. [ ] CHANGE IN INFORMATION
- d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:16-NOV-2017
DISTRICT: New Orleans
PRINTED BY FDA:27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO. FEI: 0300916996
c. DRUG FDA 2656 NO.

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

600 Luckie Drive
Suite 315
Birmingham, Alabama 35223

a. PHONE 205-533-7709 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)
NuTech Spine and Biologics
Attn: Rachel Cromer, AL
600 Luckie Drive
Suite 315
Birmingham, Alabama 35223

a. PHONE 205-533-7709 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Rachel Cromer, AL
b. E-MAIL rcromer@nutechspine.com
c. TITLE Quality Director d. DATE 16-NOV-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		NuFix, SIFix, DuALIF
b. Cartilage						X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia						X		X	X			
g. Heart Valve												
h. Ligament						X		X	X			
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium						X		X	X			
k. Peripheral Blood Stem [ ] Autologous [ ] Family Related [ ] Allogeneic												
l. Sclera												
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin						X		X	X			GammaGraft
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon						X		X	X			
q. Umbilical Cord Blood [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft												
s.												
t.												
u.												
v.												