

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
(Field 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:18-AUG-2010
DISTRICT: New Orleans
PRINTED BY FDA:18-AUG-2010

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

- a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2658 NO.

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

Nutech Medical, 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)*

Nutech Medical, Inc.
Attn: Rita K. Turner, CTBS
2641 Rocky Ridge Lane
Birmingham, Alabama 35216

- 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. Turner, CTBS

b. E-MAIL rturner@nutechmedical.com

c. TITLE Tissue/Office Manager

d. DATE 17-AUG-2010

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions								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)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. Bone						X		X	X			NuFix, NuFix II, NuFix SPIF
b. Cartilage						X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo												
f. Fascia						X		X	X			
g. Heart Valve												
h. Ligament						X		X	X			
i. Oocyte												
j. Pericardium						X		X	X			
k. Peripheral Blood Stem Cells												
l. Sclera												
m. Semen												
n. Skin						X		X	X			
o. Somatic Cell Therapy Products												
p. Tendon						X		X	X			
q. Umbilical Cord Blood Stem Cells												
r. Vascular Graft												
s. Amniotic Membrane						X		X	X			NuCel, NuShield, BioArthro
t. Nerve Tissue						X		X	X			
u.												
v.												