

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: 3006717666

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:29-JUN-2011
DISTRICT: Los Angeles
PRINTED BY FDA:29-JUN-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

- a. BLOOD FDA 2630 NO. _____
b. DEVICES FDA 2891 NO. FEI: 3003415347
c. DRUG FDA 2656 NO. _____

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

Bio-Tissue, Inc - San Diego
11315 Rancho Bernardo Road
Suite 135
San Diego, California 92127

- a. PHONE 800-990-1306 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)

Bio-Tissue, Inc.
Attn: Topaz J. Kirlew, MT(ASCP), DBA
7000 SW 97th Avenue, Suite 211
Miami, Florida 33173

- a. PHONE (305)412-4430 EXT 214

7. ENTER CORRECTIONS TO ITEM 6

b. PHONE _____

8. U.S. AGENT

a. E-MAIL _____

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Topaz J. Kirlew, MT(ASCP), DBA

b. E-MAIL tkirlew@biotissue.com

c. TITLE Executive Vice President

d. DATE 28-JUN-2011

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 1271.19	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL PRODUCTS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
j. Pericardium												
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
l. Sclera												
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
n. Skin												
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
p. Tendon												
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
r. Vascular Graft												
s. Amniotic Membrane						X		X	X	X	*** See full text on next page	
t. Placenta						X		X	X		AmnioPatch (Tissue Graft)	
u.												
v.												

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: 3006717666

ADDITIONAL INFORMATION:

Satellite Distribution Facility of Bio-Tissue, Inc and Amnio Medical

Proprietary Name(s):

. Amniotic Membrane AmnioGraft, AmnioGuard, NEOX 100 & NEOX 1K
(tissue grafts); ProKera (medical device)