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: 3000779542

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:31-JUL-2018
DISTRICT: Dallas
PRINTED BY FDA:27-SEP-2018

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)

Bone Bank Allografts

5335 Castroville Road
San Antonio, Texas 78227

a. PHONE 210-696-7616 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)

Bone Bank Allografts
Attn: Christy L. Martinelli
5335 Castroville Road
San Antonio, Texas 78227

a. PHONE 210-696-7616 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Christy L. Martinelli

b. E-MAIL cmartinelli@bonebank.com

c. TITLE Director of Quality Assurance d. DATE 30-JUL-2018

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	X			*** See full text on next page
b. Cartilage		X				X	X	X	X			SteriGraft
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia		X				X	X	X	X			SteriGraft
g. Heart Valve												
h. Ligament		X				X	X	X	X			SteriGraft
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium		X				X	X	X	X			SteriGraft
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin		X				X	X	X	X			SteriMatrix, FlowerDerm
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon		X				X	X	X	X			SteriGraft
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft												
s. Amniotic Membrane		X				X	X	X	X			*** See full text on next page
t. Amniotic Fluid		X				X	X	X	X			*** See full text on next page
u.												
v.												

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ADDITIONAL INFORMATION:

Proprietary Name(s):

a. Bone	SteriGraft, SteriSorb, SteriFlex, SteriFuse, SteriScaf HSA
Amniotic Membrane	SteriShield, SteriShield II, FlowerPatch, FlowerAmnioPatch, AmnioArmor
Amniotic Fluid	Amnios, SteriFlo, Amnios RT, FlowerFlo, FlowerAmnioFlo