

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3000779542	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:25-NOV-2015 DISTRICT: Dallas PRINTED BY FDA:03-DEC-2015
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION								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)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Establishment Functions											
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute			
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Bone Bank Allografts  4808 Research Drive San Antonio, Texas 78240  a. PHONE 210-696-7616 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	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 <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	f. Fascia		X				X	X	X	X		SteriGraft
	g. Heart Valve											
	h. Ligament		X				X	X	X	X		SteriGraft
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	j. Pericardium		X				X	X	X	X		SteriGraft
	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											
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	n. Skin		X				X	X	X	X		SteriMatrix
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Bone Bank Allografts Attn: James Poser 4808 Research Drive San Antonio, Texas 78240  a. PHONE 800.397.0088 EXT _____	p. Tendon		X				X	X	X	X		SteriGraft
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	r. Vascular Graft											
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____	s. Amniotic Membrane		X				X	X	X	X		SteriShield
	t. Amniotic Fluid		X				X	X	X	X		AmniOs
	u.											
	v.											
<b>8. U.S. AGENT</b>  a. E-MAIL _____												
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME James Poser b. E-MAIL jposer@bonebank.com c. TITLE Chief Technology Officer d. DATE 24-NOV-2015												

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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

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**ADDITIONAL INFORMATION:**

Bone Bank Allografts satellite facility utilized for storage only  
located at:

5335 Castroville Road  
San Antonio, TX 78227

**Proprietary Name(s):**

a. Bone SteriGraft, SteriSorb, SteriFlex, SteriFuse