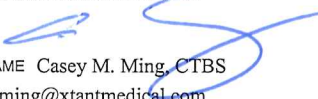


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3005168462	2. REASON FOR SUBMISSION 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	VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:01-DEC-2016 DISTRICT: Seattle PRINTED BY FDA:15-DEC-2016												
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 3005168462 c. DRUG FDA 2656 NO. _____		PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps						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)					
		Establishment Functions														
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute						
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Bacterin International Inc. 600 Cruiser Lane Belgrade, Montana 59714 a. PHONE 406-388-0480 EXT 1128 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	X	X	X	X	*** See full text on next page		
		b. Cartilage		X		X	X	X	X	X	X					
		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	X	X	X			hMatrix	
		g. Heart Valve														
		h. Ligament			X		X	X	X	X	X	X				
		i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		j. Pericardium			X		X	X	X	X	X	X				
		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													
		5. ENTER CORRECTIONS TO ITEM 4		n. Skin		X		X	X	X	X	X	X			hMatrix Dermis, hMatrix PR
o. Somatic Cell Therapy Products	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic								X		X	X			OsteoVive	
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Bacterin International, Inc. Attn: Casey M. Ming, CTBS 600 Cruiser Lane Belgrade, Montana 59714 a. PHONE 406.388.0480 EXT 1128		p. Tendon		X		X	X	X	X	X	X			SportMatrix		
		q. Umbilical Cord Blood	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
		r. Vascular Graft														
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____		s.														
		t.														
		u.														
		v.														
		8. U.S. AGENT a. E-MAIL _____		9. REPORTING OFFICIAL'S SIGNATURE 												
a. TYPED NAME Casey M. Ming, CTBS																
b. E-MAIL cming@xtantmedical.com																
c. TITLE Regulatory Affairs Manager										d. DATE 30-NOV-2016						

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: 3005168462

ADDITIONAL INFORMATION:

Proprietary Name(s):

- a. Bone OsteoSponge, OsteoSelect DBM Putty (and Plus),
OsteoWrap, Orbital Wrap HD, OsteoLock, BacFast
HD, OsteoSTX, 3Demin