

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: 3007717495	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:01-MAR-2017 DISTRICT: New Orleans PRINTED BY FDA:17-MAR-2017
---	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION														14. PROPRIETARY NAME(S)		
3. OTHER FDA REGISTRATIONS	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					
	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) BioDlogics LLC 7740A Trinity Road Suite 107 Cordova, Tennessee 38018 a. PHONE 901-417-7868 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							
	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																
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) BioDlogics LLC Attn: Michael S. Scott, MS 7740A Trinity Road Suite 107 Cordova, Tennessee 38018 a. PHONE 901-417-7868 EXT _____	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																
	9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Michael S. Scott, MS b. E-MAIL mscott@biodllc.com c. TITLE VP, Quality and Regulatory Affairs d. DATE 28-FEB-2017	s. Amniotic Membrane	X	X		X	X	X	X	X	X						*** See full text on next page
		t. Placenta	X	X		X	X	X	X	X	X						*** See full text on next page
u.																	
v.																	
7. ENTER CORRECTIONS TO ITEM 4																	
5. ENTER CORRECTIONS TO ITEM 6																	
8. U.S. AGENT																	

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: 3007717495

ADDITIONAL INFORMATION:

Change in Ownership Effective February 24, 2016: Integra
LifeSciences Holdings Corporation acquired Derma Sciences, Inc.,
for which BioDlogics, LLC is a wholly owned subsidiary.

Proprietary Name(s):

Amniotic	AmnioExCel, Armor, BioDOptix, BioDDryFlex,
Membrane	Meta-Link-H, Meta-Link-D, BioDfence G3, BioDfence Sentry
Placenta	BioDfactor, AmnioMatrix, Prime, BioDRestore, Meta- Link