

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: 3005897621	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:27-DEC-2017 DISTRICT: Atlanta PRINTED BY FDA:27-JAN-2018
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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									
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	Establishment Functions												
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) MiMedx Tissue Services, LLC 1775 West Oak Commons Court NE Marietta, Georgia 30062 a. PHONE 770-651-9254 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone																					
	b. Cartilage																					
	c. Cornea																					
5. ENTER CORRECTIONS TO ITEM 4	d. Dura Mater																					
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
	f. Fascia																					
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) MiMedx Tissue Services, LLC Attn: Mark Rogers 1775 West Oak Commons Ct NE Marietta, Georgia 30062 a. PHONE 770-651-9254 EXT _____	g. Heart Valve																					
	h. Ligament																					
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
7. ENTER CORRECTIONS TO ITEM 6 a. PHONE 770-651-9254 EXT _____ b. PHONE _____	j. Pericardium																					
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																					
	l. Sclera																					
8. U.S. AGENT a. E-MAIL _____	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																					
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Mark Rogers b. E-MAIL mrogers@mimedx.com c. TITLE VP, QA/RA d. DATE 27-DEC-2017	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	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. Amniotic Fluid	X	X		X	X	X	X	X	X												*** See full text on next page
	v. Umbilical Cord	X	X		X	X	X	X	X	X												*** See full text on next page

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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: 3005897621

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ADDITIONAL INFORMATION:

- s. Amniotic Membrane: AmbioDisk, Ambio2, Ambio5, AmnioFix, AmnioCore, AmnioRepair, AmnioShield, AmnioVantage, AmnioVo, BioCover2, BioXclude, EpiBurn, EpiFix, EpiXL, RDX2, OcuFix1, OcuFix2, Provenda
- t. Placenta: AmnioFill
- u. Umbilical Cord: AmnioCord, AmnioCore Cord, AmnioVantage, EpiCord, Provenda
- v. Amniotic Fluid: AmnioFlo, OrthoFlo, AmnioCore

Proprietary Name(s):