

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 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:17-MAR-2017 DISTRICT: Atlanta PRINTED BY FDA:17-MAR-2017
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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 a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> </table>	Types of HCT / Ps	Establishment Functions								Recover	Screen	Test	Package	Process	Store	Label	Distribute				
Types of HCT / Ps	Establishment Functions																					
	Recover	Screen	Test	Package	Process	Store	Label	Distribute														
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										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																					
	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 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 _____ 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	n. Skin											X										
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																					
8. U.S. AGENT a. E-MAIL _____	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 Mark Rogers b. E-MAIL mrogers@mimedx.com c. TITLE VP, QA/RA d. DATE 16-MAR-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. Amniotic Fluid		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

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

2

**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)

FEI: 3005897621

ADDITIONAL INFORMATION:

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

Proprietary Name(s):