

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: 3000215346	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:23-JUL-2018 DISTRICT: Denver PRINTED BY FDA:14-SEP-2018												
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 3000215346 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)							
		Types of HCT / Ps	Establishment Functions													
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) AlloSource 6278 South Troy Circle Centennial, Colorado 80111 a. PHONE 720-873-0213 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY 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) AlloSource Attn: Trevor Wright, 6278 South Troy Circle Centennial, Colorado 80111 a. PHONE 720.873.4733 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ 8. U.S. AGENT a. E-MAIL 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Trevor Wright, b. E-MAIL twright@allosource.org c. TITLE Director of Regulatory Affairs d. DATE 23-JUL-2018		Recover	Screen	Test	Package	Process	Store	Label	Distribute							
		a. Bone		X		X	X	X	X	X	X	X	X	X	*** See full text on next page	
		b. Cartilage			X		X	X	X	X	X	X	X	X	DeNovo NT, ProChondrix (Fresh, CR)	
		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	X	X		
		g. Heart Valve														
		h. Ligament			X		X	X	X	X	X	X	X	X		
		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														
		n. Skin		X		X	X	X	X	X	X	X	X	X	AlloSkin (RT, AC), AlloMend, PureSkin	
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
		p. Tendon			X		X	X	X	X	X	X	X	X	RcConnex	
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
		r. Vascular Graft					X	X	X	X	X	X	X	X	X	
		s. Amniotic Membrane			X		X	X	X	X	X	X	X	X	AlloWrap (DS, Dry)	
t. Placenta		X	X		X						X					
u.																
v.																

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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)

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(FDA Establishment Identifier)

FEI: 3000215346

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ADDITIONAL INFORMATION:

Proprietary Name(s):

a. Bone AlloFuse (DBM, Plus DBM, Cortical Fibers, Fiber
Boat, Select CM, Cervical Spacer), AlloFlex, AlloGro,
AlloPac