

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: 3001451326	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:17-NOV-2016 DISTRICT: Atlanta PRINTED BY FDA:15-DEC-2016
---	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																																																																																																																																																																																																																																																																																																																																
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 0001063481 c. DRUG FDA 2656 NO. _____	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th rowspan="2" style="width:40%;">10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</th> <th colspan="9">Establishment Functions</th> <th rowspan="2" style="width:5%;">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="width:5%;">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="width:5%;">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2" style="width:15%;">14. PROPRIETARY NAME(S)</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> <tr> <td style="vertical-align: top;"> 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) CryoLife, Inc. 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 a. PHONE 770-419-3355 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY </td> <td style="vertical-align: top;"> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:40%;">a. Bone</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>b. Cartilage</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>c. Cornea</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>d. Dura Mater</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>f. Fascia</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>g. Heart Valve</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">CryoValve, CryoValve SG</td> </tr> <tr> <td>h. Ligament</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>j. Pericardium</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td style="text-align: center;">CryoPatch</td> </tr> <tr> <td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>l. Sclera</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>n. Skin</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>p. Tendon</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>r. Vascular Graft</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">*** See full text on next page</td> </tr> <tr> <td>s. Amniotic Membrane</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td style="text-align: center;">NeoPatch</td> </tr> <tr> <td>t.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>u.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>v.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table> </td> </tr> <tr> <td style="vertical-align: top;"> 5. ENTER CORRECTIONS TO ITEM 4 </td> <td></td> </tr> <tr> <td style="vertical-align: top;"> 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) CryoLife, Inc. Attn: Rochelle Maney 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 a. PHONE 770-419-3355 EXT 4531 </td> <td></td> </tr> <tr> <td style="vertical-align: top;"> 7. ENTER CORRECTIONS TO ITEM 6 </td> <td></td> </tr> <tr> <td style="vertical-align: top;"> 8. U.S. AGENT a. E-MAIL </td> <td></td> </tr> <tr> <td style="vertical-align: top;"> 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Rochelle Maney b. E-MAIL maney.rochelle@cryolife.com c. TITLE Director, Regulatory Compliance </td> <td style="vertical-align: top;"> d. DATE 16-NOV-2016 </td> </tr> </table>	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps	Establishment Functions									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)	Recover	Screen	Test	Package	Process	Store	Label	Distribute	4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) CryoLife, Inc. 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 a. PHONE 770-419-3355 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:40%;">a. Bone</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>b. Cartilage</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>c. Cornea</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>d. Dura Mater</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>f. Fascia</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>g. Heart Valve</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">CryoValve, CryoValve SG</td> </tr> <tr> <td>h. Ligament</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>j. Pericardium</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td style="text-align: center;">CryoPatch</td> </tr> <tr> <td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>l. Sclera</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>n. Skin</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>p. Tendon</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>r. Vascular Graft</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">*** See full text on next page</td> </tr> <tr> <td>s. Amniotic Membrane</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td style="text-align: center;">NeoPatch</td> </tr> <tr> <td>t.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>u.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>v.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>	a. Bone													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		X	X	X	X	X	X	X	X	X		CryoValve, CryoValve SG	h. Ligament													i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													j. Pericardium		X	X	X	X	X	X	X	X			CryoPatch	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		X	X	X	X	X	X	X	X	X		*** See full text on next page	s. Amniotic Membrane		X	X	X	X	X	X	X	X			NeoPatch	t.													u.													v.													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) CryoLife, Inc. Attn: Rochelle Maney 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 a. PHONE 770-419-3355 EXT 4531		7. ENTER CORRECTIONS TO ITEM 6		8. U.S. AGENT a. E-MAIL		9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Rochelle Maney b. E-MAIL maney.rochelle@cryolife.com c. TITLE Director, Regulatory Compliance	d. DATE 16-NOV-2016
10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps	Establishment Functions									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)																																																																																																																																																																																																																																																																																																																
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																																																																																									
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) CryoLife, Inc. 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 a. PHONE 770-419-3355 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:40%;">a. Bone</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>b. Cartilage</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>c. Cornea</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>d. Dura Mater</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>f. Fascia</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>g. Heart Valve</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">CryoValve, CryoValve SG</td> </tr> <tr> <td>h. Ligament</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>j. Pericardium</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td style="text-align: center;">CryoPatch</td> </tr> <tr> <td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>l. Sclera</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>n. Skin</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>p. Tendon</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>r. Vascular Graft</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">*** See full text on next page</td> </tr> <tr> <td>s. Amniotic Membrane</td> <td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td style="text-align: center;">NeoPatch</td> </tr> <tr> <td>t.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>u.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>v.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>	a. Bone													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		X	X	X	X	X	X	X	X	X		CryoValve, CryoValve SG	h. Ligament													i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													j. Pericardium		X	X	X	X	X	X	X	X			CryoPatch	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		X	X	X	X	X	X	X	X	X		*** See full text on next page	s. Amniotic Membrane		X	X	X	X	X	X	X	X			NeoPatch	t.													u.													v.																																														
a. Bone																																																																																																																																																																																																																																																																																																																																	
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		X	X	X	X	X	X	X	X	X		CryoValve, CryoValve SG																																																																																																																																																																																																																																																																																																																					
h. Ligament																																																																																																																																																																																																																																																																																																																																	
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																	
j. Pericardium		X	X	X	X	X	X	X	X			CryoPatch																																																																																																																																																																																																																																																																																																																					
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		X	X	X	X	X	X	X	X	X		*** See full text on next page																																																																																																																																																																																																																																																																																																																					
s. Amniotic Membrane		X	X	X	X	X	X	X	X			NeoPatch																																																																																																																																																																																																																																																																																																																					
t.																																																																																																																																																																																																																																																																																																																																	
u.																																																																																																																																																																																																																																																																																																																																	
v.																																																																																																																																																																																																																																																																																																																																	
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) CryoLife, Inc. Attn: Rochelle Maney 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 a. PHONE 770-419-3355 EXT 4531																																																																																																																																																																																																																																																																																																																																	
7. ENTER CORRECTIONS TO ITEM 6																																																																																																																																																																																																																																																																																																																																	
8. U.S. AGENT a. E-MAIL																																																																																																																																																																																																																																																																																																																																	
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Rochelle Maney b. E-MAIL maney.rochelle@cryolife.com c. TITLE Director, Regulatory Compliance	d. DATE 16-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: 3001451326

2

ADDITIONAL INFORMATION:

Proprietary Name(s):

r. Vascular Graft CryoVein, CryoArtery, CryoGraft, CryoPatch,
CryoPatch SG