

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 0001287163	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:16-NOV-2017 DISTRICT: New England PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																																																																																																																																																																																																																																																																																																
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 0001287163 c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">11. HCT/PS DESCRIBED IN 21 OF 171.10</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">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> </thead> </table>	Types of HCT / Ps	Establishment Functions								11. HCT/PS DESCRIBED IN 21 OF 171.10	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																																																																																																																																																																																																																																																																											
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<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Ace Surgical Supply CO. INC  1034 Pearl Street Brockton, Massachusetts 02301  a. PHONE 800-441-3100 EXT 215 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>a. Bone</td> <td></td><td></td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td> <td></td><td></td><td>*** See full text on next page</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. 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<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Ace Surgical Supply CO. INC Attn: Kathy Strange 1034 Pearl Street Brockton, Massachusetts 02301  a. PHONE 800-441-3100 EXT 215																																																																																																																																																																																																																																																																																																	
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<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Kathy Strange b. E-MAIL kathystrange@acesurgical.com c. TITLE Director of Regulatory Affairs- Quality d. DATE 16-NOV-2017																																																																																																																																																																																																																																																																																																	

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: 0001287163

2

**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

a. Bone Newport Biologics; bioGRAF; RAPTOS, AlloOss;  
OUSIA; SYMBIOS; REGENX, Puragraft, Citagenix