

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: 3008778079	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:13-JAN-2017 DISTRICT: New Jersey PRINTED BY FDA:03-FEB-2017
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION	11. HCT/PS DESCRIBED IN 21 OFK 12/1/10	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" style="width:30%;">Types of HCT / Ps</th> <th colspan="9" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="width:5%;">11. HCT/PS DESCRIBED IN 21 OFK 12/1/10</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:10%;">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th style="width:5%;">Recover</th> <th style="width:5%;">Screen</th> <th style="width:5%;">Test</th> <th style="width:5%;">Package</th> <th style="width:5%;">Process</th> <th style="width:5%;">Store</th> <th style="width:5%;">Label</th> <th style="width:5%;">Distribute</th> </tr> </thead> </table>					Types of HCT / Ps	Establishment Functions									11. HCT/PS DESCRIBED IN 21 OFK 12/1/10	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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4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Xytex Laboratories 303 George Street Suite G30 New Brunswick, New Jersey 08091 a. PHONE 706-733-0130 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:30%;">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><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><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><td></td> </tr> <tr> <td>d. 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6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Xytex Laboratories Attn: James T. Spradlin M.D. 1100 Emmett Street Augusta, Georgia 30904 a. PHONE 706 733 0130 EXT _____					
7. ENTER CORRECTIONS TO ITEM 6					
8. U.S. AGENT a. E-MAIL _____					
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME James T. Spradlin M.D. b. E-MAIL tspradlin@xytex.com c. TITLE Chief Medical & Laboratory Director d. DATE 12-JAN-2017					