

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: 3009234552	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:21-NOV-2017 DISTRICT: Dallas PRINTED BY FDA:27-JAN-2018																																																																																																																																																																																																																																																	
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>							11. HCT/PS DESCRIBED IN 21 CFR 1271.110 12. HCT/PS REGULATED AS MEDICAL DEVICES 13. HCT/PS DESIGNED AS DRUGS OR BIOLOGICAL DRUGS	<b>14. PROPRIETARY NAME(S)</b>																																																																																																																																																																																																																																											
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ 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="text-align: center;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> </tr> <tr> <th style="text-align: center;">Recover</th> <th style="text-align: center;">Screen</th> <th style="text-align: center;">Test</th> <th style="text-align: center;">Package</th> <th style="text-align: center;">Process</th> <th style="text-align: center;">Store</th> <th style="text-align: center;">Label</th> <th style="text-align: center;">Distribute</th> </tr> </thead> <tbody> <tr> <td>a. 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**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,  
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(See reverse side for instructions)

**1. REGISTRATION NUMBER**  
(FDA Establishment Identifier)

FEI: 3009234552

**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

a. Bone MatrixOI, FlexIT, Influx, MatrixCollect 100 DBM  
Putty, MatrixCollect 100 DBM Crunch, ConCelltrate  
100, DentalFix