

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) <i>(See reverse side for Instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3001237888	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 *3001237888* VALIDATED By FDA:12/10/07 PRINTED By FDA:12/17/07 DISTRICT: Atlanta
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																																																																																																																																																																																																																																																																																																																																																						
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:15%;">Types of HCT / Ps</th> <th colspan="9" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="width:10%;">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="width:10%;">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="width:10%;">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2" style="width:10%;">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> <tbody> <tr> <td style="text-align: center;">No HCT / P Specified</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>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. 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4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) The North Carolina Eye Bank, Inc 3900 West Point Boulevard, Suite F Winston Salem, North Carolina 27103 a. PHONE 336-765-0932 EXT 9300 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) The North Carolina Eye Bank, Inc. Attn: Jens Saakvitne 3900 WestPoint Boulevard Suite F Winston Salem, North Carolina 27103 a. PHONE 336-765-0932 EXT 9300	7. ENTER CORRECTIONS TO ITEM 6																																																																																																																																																																																																																																																																																																																																																						
8. U.S. AGENT a. E-MAIL	9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Jens Saakvitne b. E-MAIL jsaakvitne@nceyebank.org c. TITLE Executive Director d. DATE 05-DEC-2007																																																																																																																																																																																																																																																																																																																																																						

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**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(Field Establishment Identifier)
FEI: 3001237888

ADDITIONAL INFORMATION:

Amniotic membrane (Ambiodry) NCEB distributes on request

Proprietary Name(s):