FORM APPROVED: OMB No. 0910-0052. Expiration Date: March 31, 2015. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
FEI: 1074242
CFN: 1074242

2. U.S. LICENSE NUMBER

3. REASON FOR SUBMISSION
.1 ☑ ANNUAL REGISTRATION
.2 ☐ INITIAL REGISTRATION
.3 ☐ CHANGE IN INFORMATION

FOR FDA USE ONLY 1

DISTRICT OFFICE: Atlanta
VALIDATED BY FDA: 21-NOV-2013
PRINTED BY FDA: 05-DEC-2013

PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in item 4, and any changes in your mailing address in item 6. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 8.3 and the phone number of your actual location in item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.

This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) and can result in a fine of up to $1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 33.3(a)).

ENTER ALL CHANGES IN RED INK AND CIRCLE.

4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code)

Duke University Medical Center Duke Hospital North
Room 1720
Box 2928
Durham, NC 27710

4.1 PHONE 919-681-2644

5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.)

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

Duke University Medical Center
ATTN: Nicholas . Bandarenko
Box 2928
Durham, NC 27710

7. U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code)

7.1 E-MAIL ADDRESS
7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE

8.1 TYPED NAME Nicholas . Bandarenko
8.2 E-MAIL ADDRESS nick.b@duke.edu
8.3 PHONE 919-681-4666 8.4 DATE

9. TYPE OF OWNERSHIP
.1 ☐ SINGLE PROPRIETORSHIP
.2 ☐ PARTNERSHIP
.3 ☑ CORPORATION profit___ non-profit ✓
.4 ☐ COOPERATIVE ASSOCIATION
.5 ☐ FEDERAL (non-military)
.6 ☐ U.S. MILITARY
.7 ☐ STATE
.8 ☐ COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
.9 ☐ OTHER (Specify) :

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)
.1 ☐ COMMUNITY (NON-HOSPITAL) BLOOD BANK
.2 ☑ HOSPITAL BLOOD BANK
.3 ☐ PLASMAPHERESIS CENTER
.4 ☐ PRODUCT TESTING LABORATORY
a. ___ INDEPENDENT
___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
.5 ☐ HOSPITAL TRANSFUSION SERVICE
a. ___ APPROVED FOR MEDICARE REIMBURSEMENT
___ NOT APPROVED FOR MEDICARE REIMBURSEMENT
.6 ☐ COMPONENT PREPARATION FACILITY
.7 ☐ COLLECTION FACILITY
.8 ☐ DISTRIBUTION CENTER
U.S. LICENSE NUMBER OF PARENT FIRM
.9 ☐ BROKER/WAREHOUSE
.10 ☐ OTHER (Specify) :

11. PRODUCTS
☐ ALLOGENEIC ☐ AUTOLOGOUS ☐ DIRECTED

		COLLECT (.1)	MANUAL APHERESIS (.2)	AUTOMATED APHERESIS (.3)	PREPARE (.4)	LEUKOCYTES REDUCED (.5)	IRRADIATED (.6)	DONOR RETESTED (.7)	TEST (.8)	STORE and DISTRIBUTE to OTHERS (.9)
WHOLE BLOOD	1						X		X	
RED BLOOD CELLS (RBC)	2						X		X	
RBC FROZEN	3									
RBC DEGLYCEROLIZED	4				X		X		X	
RBC REJUVENATED	5									
RBC REJUVENATED FROZEN	6									
RBC REJUVENATED DEGLYCEROLIZED	7									
CRYOPRECIPITATED AHF	8									
PLATELETS	9						X			
LEUKOCYTES/GRANULOCYTES	10								X	
PLASMA	11									
PLASMA CRYOPRECIPITATE REDUCED	12									
FRESH FROZEN PLASMA	13									
LIQUID PLASMA	14									
THERAPEUTIC EXCHANGE PLASMA	15									
SOURCE LEUKOCYTES	16									
SOURCE PLASMA	17									
RECOVERED PLASMA	18									
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19									
BLOOD BANK REAGENTS	20									
OTHER	21									