See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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 (Field Establishment Identifier)
FEI: 3002924436

2. REASON FOR SUBMISSION
a. [ ] INITIAL REGISTRATION / LISTING
b. [ ] ANNUAL REGISTRATION / LISTING
c. [X] CHANGE IN INFORMATION
d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:05-OCT-2011
DISTRICT: Int'l Operations Group
PRINTED BY FDA:24-OCT-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO. FEI: 3002924436
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
Tutogen Medical GmbH
Industriestra Be 6
D-91077 Neunkirchen am. Brand
Neunkirchen, 91077
Germany

a. PHONE 09134-99-88-8 5 EXT 0
b. [ ] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.
c. [ ] 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)
RTI Biologics, Inc.
Attn: Cheryl L. Bagwell, CTBS
11621 Research Circle
Alachua, Florida 32615

a. PHONE 386-418-8888 EXT 4564

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT Cheryl L. Bagwell, CTBS
RTI Biologics, Inc.
11621 Research Circle, Alachua, Florida 32615

a. E-MAIL cbagwell@rtix.com 386-418-8888-4564

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Cheryl L. Bagwell, CTBS
b. E-MAIL cbagwell@rtix.com
c. TITLE Compliance Manager d. DATE 04-OCT-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a. Bone		X		X	X	X	X	X	X			
b. Cartilage		X		X	X	X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia		X		X	X	X	X	X	X			
g. Heart Valve												
h. Ligament		X		X	X	X	X	X	X			
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium		X		X	X	X	X	X	X			
k. Peripheral Blood Stem [ ] Autologous [ ] Family Related [ ] Allogeneic												
l. Sclera												
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin		X		X	X	X	X	X	X			
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon		X		X	X	X	X	X	X			
q. Umbilical Cord Blood [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft												
s.												
t.												
u.												
v.												