See Instructions for OMB Statement

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 3003651454

2. REASON FOR SUBMISSION

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:02-DEC-2009
DISTRICT: Minneapolis
PRINTED BY FDA:18-DEC-2009

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. _____

c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

ReproTech, Ltd.
550 Village Center Drive
STE 300
St Paul, Minnesota 55127

a. PHONE 651-489-0827 EXT 100

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)*

ReproTech, Ltd.
Attn: Russell C. Bierbaum, MS
550 Village Center Drive
STE 300
St Paul, Minnesota 55127

a. PHONE 651-489-0827 EXT 100

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Russell C. Bierbaum, MS

b. E-MAIL rcbierbaum@reprot.com

c. TITLE President d. DATE 01-DEC-2009

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	*Establishment Functions*								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)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo [X] SIP [X] Directed [X] Anonymous		X				X	X	X	X			
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte [X] SIP [X] Directed [X] Anonymous						X	X	X	X			
j. Pericardium												
k. Peripheral Blood Stem [ ] Autologous [ ] Family Related [ ] Allogeneic												
l. Sclera												
m. Semen [X] SIP [X] Directed [X] Anonymous						X	X	X	X			
n. Skin												
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon												
q. Umbilical Cord Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft												
s. Ovarian Tissue						X	X	X	X			
t. Testicular Tissue						X	X	X	X			
u.												
v.												

FORM FDA 3356 (4/08)