

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
(FDA Establishment Identifier)
FEI: 3007952886

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

VALIDATION - FOR FDA USE ONLY
VALIDATED BY FDA: 16-NOV-2016
DISTRICT: Dallas
PRINTED BY FDA: 15-DEC-2016

| PART I - ESTABLISHMENT INFORMATION | | PART II - PRODUCT INFORMATION | | | | | | | | | | | | |
|--|--|---|---|-------------------------|---------|---------|-------|-------|------------|-------------------------------------|--|---|--|--|
| 3. OTHER FDA REGISTRATIONS | | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS | | | | | | | | | | | | |
| | | Types of HCT / PS | | Establishment Functions | | | | | | 14. PROPRIETARY NAME(S) | | | | |
| | | Recover | Screen | Test | Package | Process | Store | Label | Distribute | 11. HCT/PS DESCRIBED IN CFR 1271.10 | 12. HCT/PS REGULATED AS BIOLOGICAL DRUGS | 13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS | | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Parametrics Medical, LLC 1930 Rawhide Drive #410 Round Rock, Texas 78681 | | a. Bone | | | | | | X | | | X | | | |
| | | b. Cartilage | | | | | X | | | | X | | | |
| | | c. Cornea | | | | | | | | | | | | |
| | | d. Dura Mater | | | | | X | | | | X | | | |
| | | e. Embryo | <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | |
| | | f. Fascia | | | | | X | | | | X | | | |
| | | g. Heart Valve | | | | | | | | | | | | |
| | | h. Ligament | | | | | X | | | | X | | | |
| | | i. Oocyte | <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | |
| | | j. Pericardium | | | | | | | | | | | | |
| | | k. Peripheral Blood Stem | <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | |
| | | l. Sclera | | | | | | | | | | | | |
| | | m. Semen | <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | |
| | | n. Skin | | | | | X | | | | X | | | |
| | | o. Somatic Cell Therapy Products | <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | |
| | | p. Tendon | | | | | X | | | | X | | | |
| | | q. Umbilical Cord Blood | <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | |
| | | r. Vascular Graft | | | | | | | | | | | | |
| | | s. Amniotic Membrane | | | | | X | | | | X | | | |
| | | t. | | | | | | | | | | | | |
| | | u. | | | | | | | | | | | | |
| | | v. | | | | | | | | | | | | |

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)
Parametrics Medical, LLC
Attn: Charles G. Hall
1930 Rawhide Dr #410
Round Rock, Texas 78681

7. ENTER CORRECTIONS TO ITEM 6
a. PHONE 512-656-1846 EXT _____
b. PHONE _____

8. U.S. AGENT
a. E-MAIL _____

9. REPORTING OFFICIAL'S SIGNATURE
a. TYPED NAME Charles G. Hall
b. E-MAIL chuck@parametricmedical.com
c. TITLE Director
d. DATE 15-NOV-2016