See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017 DEPARTMENT OF HEALTH AND HUMAN SERVICES 2. REASON FOR SUBMISSION 1. REGISTRATION NUMBER VALIDATION--FOR FDA USE ONLY PUBLIC HEALTH SERVICE (FDA Establishment Identifier) INITIAL REGISTRATION / LISTING VALIDATED BY FDA:15-DEC-2016 FOOD AND DRUG ADMINISTRATION DISTRICT: New England ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, b. X ANNUAL REGISTRATION / LISTING FEI: 1000148471 PRINTED BY FDA:28-DEC-2016 AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) CHANGE IN INFORMATION (See reverse side for instructions) d. | INACTIVE PART I - ESTABLISHMENT INFORMATION **PART II - PRODUCT INFORMATION** 11. HCT/Ps DESCRIBED IN 21 CFR 1271.10 12. HCT/Ps REGULATED AS MEDICAL DEVICES 3. OTHER FDA REGISTRATIONS 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps a. BLOOD FDA 2830 14. PROPRIETARY **Establishment Functions** NAME(S) Types of HCT / Ps NO. FEI: 1000148471 b. DEVICES FDA 2891 Recover Screen Test Package Label Distribute Process Store c. DRUG FDA 2656 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and a. Bone post office code) Organogenesis Inc. b. Cartilage 150 Dan Road c. Cornea Canton, Massachusetts 02021 d. Dura Mater SIP Directed e. Embryo a. PHONE 781-401-1155 Anonymous b. SATELLITE RECOVERY ESTABLISHMENT f. Fascia (MANUFACTURING ESTABLISHMENT FEI NO TESTING FOR MICRO-ORGANISMS ONLY g. Heart Valve 5. ENTER CORRECTIONS TO ITEM 4 h. Ligament ☐ SIP Directed 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, i. Oocyte number and street, city, state, country, and post office code) Anonymous Organogenesis Inc. i. Pericardium Attn: Patrick Bilbo 150 Dan Road k. Peripheral Autologous ☐ Family Related **Blood Stem** Canton, Massachusetts 02021

Allogeneic I. Sclera SIP Directed a. PHONE 781-401-1155 m. Semen EXT Anonymous 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE X X n. Skin X X X X X X Apligraf o. Somatic Cell Autologous Therapy ☐ Family Related **Products** Allogeneic 8. U.S. AGENT p. Tendon q. Umbilical Autologous Cord Blood ☐ Family Related Allogéneic

r. Vascular Graft

s.

u.

٧.

a. TYPED NAME Patrick Bilbo b. E-MAIL pbilbo@organo.com

9. REPORTING OFFICIAL'S SIGNATURE

a. E-MAIL

c. TITLE SVP, Regulatory, Government Affairs, Adm d. DATE 14-DEC-2016