9. REPORTING OFFICIAL'S SIGNATURE a. PHONE 215-218-7100
7. ENTER CORRECTIONS TO ITEM 6 b. E-MAIL michael.mccormick@wuxiapptec.com c. TITLE V.P., Quality Assurance a E-MAIL 8. U.S. AGENT MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code) 5. ENTER CORRECTIONS TO ITEM 4 post office code) 3. OTHER FDA REGISTRATIONS 1. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and TYPED NAME Michael McCormick a. PHONE 215-218-7100 EX
b. SATELLITE RECOVERY ESTABLISHMENT
b. MANUFACTURING ESTABLISHMENT FEI NO.
c. TESTING FOR MICRO-ORGANISMS ONLY PART I - ESTABLISHMENT INFORMATION 4751 League Island Blvd (Contract Manufacturing) 4751 League Island Blvd. WuXi AppTec Inc. (Contract Manufacturing) Attn: Michael McCormick WuXi AppTec Inc. Philadelphia, Pennsylvania Philadelphia, Pennsylvania 19112 b. DEVICES FDA 2891 c. DRUG FDA 2656 a. BLOOD FDA 2830 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) DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE 19112 NO NO S FEI: 0002247110 EXT 5543 EXT b. PHONE 5543 d DATE 27-DEC-2017 q. Umbilical Cord Blood k. Peripheral Blood Stem 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps n. Skin p. Tendon r. Vascular Graft o. Somatic Cell m. Semen i. Oocyte h. Ligament g. Heart Valve e. Embryo d. Dura Mater c. Comea b. Cartilage a, Bone , Pericardium f. Fascia Sciera PART II - PRODUCT INFORMATION Ovarian Tissue Amniotic Membrane Therapy Products Types of HCT / Ps Autologous
Family Related
Allogeneic Autologous
Family Related
Allogeneic Autologous
Family Related
X Allogeneic ☐ SIP ☐ Directed ☐ Anonymous ☐ SIP ☐ Directed ☐ Anonymous ☐ SIP Directed Anonymous 1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 1000122198 Recover Screen Test **Establishment Functions** Package Process × × 2. REASON FOR SUBMISSION 0 20 Instructions for OMB Statement INITIAL REGISTRATION / LISTING
X ANNUAL REGISTRATION / LISTING × × CHANGE IN INFORMATION × × × Store × × × × Label × × × × × FORM APPROVED:OMB No.0910-0543. Expiration Date: 6/30/2020 × 11. HCT/Ps DESCRIBED IN 21 CFR 1271.10 × VALIDATION.-FOR FDA USE ONLY VALIDATED BY FDA:27-DEC:2017 DISTRICT: Philadelphia
PRINTED BY FDA:27-JAN-2018 12. HCT/Ps REGULATED AS MEDICAL DEVICES 13. HCTIPs PRUGS OR BIOLOGICAL DRUGS × × IND / Pre IND Client Product NuCel, ReNu IND / Pre IND Client Product IND / Pre IND Client Product IND / Pre IND Client Product 14. PROPRIETARY NAME(S)