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HYLAJEL MATRIX HCT/P ALLOGRAFT FOR HOMOLOGOUS USE

PRODUCT OPTIONS

HYLAJEL – 0.5mL (4 pack)

HYLAJEL

is a minimally manipulated, bio-ethical, human umbilical cord harvested product from donated human tissue manufactured under GTP, cGMP, AATB, and FDA HCT/P 361 guidelines for homologous use in clinical settings. HYLAJEL is DMSO free, and our proprietary process is absent of harmful enzymes and chemicals to preserve integrity.

TESTING + VALIDATION:

20% of every lot manufactured is sent for sterility and endotoxin testing by a 3rd party CLIA Certified laboratory. These products are aseptically processed and packaged.

REGULATIONS:

Vitti Labs' HYLAJEL may contain live cells but does not claim that it is dependent on the metabolic activity of living cells for its primary function. HYLAJEL contains non-conduit structural tissue. HYLAJEL is not reliant on the presence nor on the metabolism of the cells in this product to create a therapeutic benefit. HYLAJEL does meet the criteria under 1271.3(d) as an HCT/P, and is regulated under 21 CFR 1271 and Section 361 of the PHS Act. Vitti Labs is an FDA registered tissue bank. We comply with FDA (Federal Drug Administration) regulations. Additionally, we are AATB (American Association of Tissue Banks) accredited, cGMP (Current Good Manufacturing Practices) certified, follow GTP (Good Tissue Practices), and WHO (World Health Organization) protocols and procedures. All VITTI LABS HCT/P products are regulated solely under section 361 of the PHS Act and the regulations in 21 CFR 1271.

MANUFACTURER'S INTENT:

HYLAJEL is a human cellular, tissue-based product (HCT/P) as defined in 21 CFR 1271.3(d), meets all of the criteria listed in 21 CFR 1271.10(a), and is therefore regulated solely under section 361 of the Public Health Service (PHS) Act (42 U.S.C.264)(Section 361 HCT/Ps). This includes following the June 2020 guidance document by the Food and Drug Administration (FDA), Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous in context to non-conduit structural tissue regulated under section 361 of the PHS Act.

* Package may be different than illustrated

VCHJ_V.03

FAQ's

Q: What is a structural tissue?
A: Tissues that physically support or serve as a barrier or conduit, or connect, cover, or cushion in the donor are generally considered structural tissues for the purposes of determining the applicable regulatory definition. Examples of structural tissues include:

- Bone
- Skin
- Amniotic membrane and umbilical cord
- Blood vessel
- Adipose tissue
- Articular cartilage
- Non-articular cartilage
- Tendon or ligament

Q: What are the meaningful characteristics of structural tissue?
A: Structural tissues utility for reconstruction, repair, and replacement uses the original relevant characteristics of structural tissues such as support, strength, flexibility, cushioning, covering, and compressibility.

Q: Do these structural tissues contain cells?
A: Structural tissues may contain both extracellular matrix and cellular components because any alteration of these components that relates to the structural tissue's utility for reconstruction, repair, or replacement would generally be considered more than minimal manipulation.

Q: What's Minimal Manipulation?
A: For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.

Q: What is Homologous Use?
A: Homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissue with an HCT/P that performs the same basic function(s) in the recipient as in the donor.

Citation: Source: Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use. Guidance for Industry and Food and Drug Administration Staff- July2020