By Electronic Mail

February 26, 2024

REDACTED
REDACTED Biologics, LLC
REDACTED
REDCATED

RE: Request for Recommendation for XWRAP® -Amniotic Membrane Allograft

Dear REDACTED:

This letter is in response to your inquiry provided to the Food and Drug Administration's Tissue Reference Group (TRG) on August 14, 2023, and subsequent communications on August 18, 2023. You are seeking a recommendation from the TRG whether XWRAP® -Amniotic Membrane Allograft, a dehydrated amnion and chorion product, is a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.

Your submission explains that the product is manufactured by REDACTED, LLC and that the submission pertains to "XWRAP (without mesh)". Your submission describes processing of the amnion and chorion membranes that includes rinsing, washing, cleaning, drying, cutting, and sterilization using irradiation. The smallest product size is 2 cm x 2 cm and you explain that XWRAP® -Amniotic Membrane Allograft is intended as a "protective barrier," "wound covering," "skin substitute graft… providing scaffolding for skin growth" and for "wound healing."

To be regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271, an HCT/P must satisfy all four criteria at 21 CFR 1271.10(a)[1]. Based on the description you provide of the processing steps and the minimum size of the product, XWRAP® -Amniotic Membrane Allograft, when intended for use as a "protective barrier" and "wound covering," appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

However, with regard to the intended use of the product as a "skin substitute graft… providing scaffolding for skin growth" and for "wound healing," these appear to be non-homologous uses of amniotic membrane. Therefore, the XWAP (without mesh) product, when intended for use as a "skin

[1] ~~The four criteria can be found at 2~~1 CFR 1271.10(a), and, as applicable, see the following guidance documents: "Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff" dated July 2020; and, "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry" dated November 2017.

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substitute graft… providing scaffolding for skin growth" and for "wound healing," does not appear to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

When an HCT/P is intended for non-homologous use, and none of the exceptions in 21 CFR 1271.15 apply, the HCT/P would be regulated by FDA as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act and/or section 351 of the PHS Act (42 U.S.C. 262) and applicable regulations, and is subject to premarket review and approval requirements.

This recommendation does not apply to any other XWRAP®-branded products manufactured by REDACTED, LLC or marketed by REDACTED, LLC. We are also aware of REDACTED application to the Centers for Medicaid & Medicare Services for the XWRAP product[2].

This letter is not a binding determination and, therefore, does not serve as a confirmation that the product meets the criteria in 21 CFR 1271.10(a) or as a classification of the product.

For questions regarding this response letter, please contact the Executive Secretary for the TRG at TissueReferenceGroup@fda.hhs.gov.

Sincerely,

Heather A. Lombardi -S
Digitally signed by Heather A. Lombardi -S
Date: 2024.02.13 11:29:50 -05'00'

Hina M. Pinto -S
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[2] Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries for Drugs, Biologicals and Radiopharmaceuticals, May 16, 2018.