By Electronic Mail

June 23, 2023

Terry Hill, MD
Stability Biologics, LLC
1077 Central Pkwy S., Suite 500
San Antonio, Texas 78232
thill@stabilitybio.com

RE: Request for Recommendation for AmnioCore Pro and AmnioCore Pro+

Dear Dr. Hill:

This letter is in response to your inquiry and communications provided to the Food and Drug Administration's Tissue Reference Group (TRG) on February 7, 2023. You are seeking a recommendation from the TRG whether your AmnioCore Pro and AmnioCore Pro+ products, are human cells, tissues, or cellular or tissue-based products (HCT/Ps) regulated solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.

Your submission describes processing the amnion and chorion membranes that includes rinsing, disinfection, and layering then sterilization with irradiation. The smallest product sizes are a 16 mm disc and a 2 cm x 3 cm sheet. You describe the AmnioCore Pro and AmnioCore Pro+ products as intended for "use as a barrier" and "applied only as a covering to offer protection from the surrounding environment."

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 products, AmnioCore Pro and AmnioCore Pro+, when intended for use as a "barrier" and "covering," appear to meet all the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

This recommendation applies solely to the AmnioCore Pro and AmnioCore Pro+ products described in your submission of February 7, 2023, when intended for use as a barrier and covering. This recommendation does not apply to any other AmnioCore branded products manufactured or marketed by Stability Biologics, LLC. Additionally, we are aware of Stability Biologics, LLC's submission to the Centers for Medicare & Medicaid Services for the "AmnioCore™" product[2].

[1] The four criteria can be found at 21 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.

[2] "Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions First Quarter, 2020 Coding Cycle for Drug and Biological Products".

Please note that this informal recommendation is based on the information you provided. Any variation from what you describe in your request for recommendation to the TRG, including but not limited to changes in the processing or proposed use, may raise additional regulatory considerations that could impact the applicability of this recommendation. For example, an amniotic membrane product, when intended for wound healing and/or to reduce scarring and inflammation would not be considered a homologous use because wound healing and reduction of scarring and inflammation are not basic functions of amniotic membrane[3].

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

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: 2023.06.23 13:01:51 -04'00'

Heather Lombardi, Ph.D.
Director
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Angela C. Krueger -S
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Angela Krueger
Deputy Director for Regulatory Policy
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

[3] See Example 19-4 in "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.