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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0881]

Consolidation of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care to Produce a Therapeutic Article

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is consolidating regulatory oversight responsibilities in the Center for Biologics Evaluation and Research (CBER) for certain devices that process autologous human cells, tissues, and cellular and tissue-based products (HCT/Ps) at the point of care where the device output is intended to mediate the intended therapeutic effect. To support this consolidation effort, fat transfer devices (described further below) with the product code MUU that are currently regulated by the Center for Devices and Radiological Health (CDRH) will be transferred to CBER for regulation. This action affects only center assignment.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130, Silver Spring, MD 20993, 301-796-8941, john.weiner@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Consolidation in CBER of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care to Produce a Therapeutic Article

FDA is consolidating regulatory oversight responsibilities in CBER for devices that process autologous human cells, tissues, and cellular and tissue-based products (HCT/Ps) at the point of care to produce a therapeutic article. To support this consolidation effort, fat transfer

devices (described further below) with the product code MUU that are currently regulated by CDRH will be transferred to CBER for regulation. This action affects only center assignment.

FDA has the authority to regulate devices as defined under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)). Devices may be regulated by CDRH or CBER (see, e.g., Ref.1).

In July 2007, the Agency published the final guidance "Devices Used to Process Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" to assist sponsors in determining which center at FDA would have regulatory oversight for devices used at the point of care to process HCT/Ps (Ref. 2). Assignment of these devices is determined by whether the point-of-care device creates an HCT/P that is intended to mediate the intended therapeutic effect. Point-of-care devices that process autologous materials are assigned to CBER when the intended therapeutic effect is mediated by the biological output of the device. For example, a cell sorter that is used to isolate CD34+ cells from bone marrow for use in hematopoietic reconstitution is assigned to CBER for review and regulation because the cellular output of the device is intended to provide the intended therapeutic effect.

Since the publication of the 2007 guidance, assignment of point-of-care devices intended to process HCT/Ps has generally been consistent with that guidance, with a few exceptions. Under 21 CFR 878.5040, a suction lipoplasty system is a Class II device that is intended for aesthetic body contouring and consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. These devices act by removal of unwanted fat from areas of the body.

However, fat transfer devices, that is, devices that process adipose tissue for return to the body, have also been regulated at CDRH and assigned the same product code, MUU, as suction lipoplasty systems. While suction lipoplasty devices for fat removal do not produce an article for return to the body in order to mediate an intended therapeutic effect, the output of fat transfer

devices is returned to the body in order to mediate the intended therapeutic effect (e.g., administration of fat for the purpose of body contouring). Accordingly, we are transferring fat transfer devices identified by product code MUU to CBER so that these devices are regulated by the same center that regulates other devices that process HCT/Ps where the device output (HCT/P) mediates the intended therapeutic effect.

This transfer does not include the suction lipoplasty devices previously in product code MUU that are solely intended to remove fat for discard for the purpose of body contouring. These devices have been assigned a new product code, QPB, and will continue to be regulated by CDRH. For the transferred MUU products, submissions, communications, and required reports should be directed to CBER. Submissions, communications, and required reports for the QPB products should continue to be directed to CDRH. Additionally, CDRH will continue to handle submissions under review or on hold (i.e., received prior to the publication date of this *Federal Register* document) for MUU products until a final decision is reached. Subsequent submissions for MUU products will be directed to CBER.

II. Reference

The following references are on display in the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500 and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at https://www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. SMG (FDA Staff Manual Guides) 1410.406, "Determination of Classification of Devices," November 13, 2018. https://www.fda.gov/media/80114/download.

2. "Guidance for industry and FDA staff Devices Used to Process Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," July 2007. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/devices-used-process-human-cells-tissues-and-cellular-and-tissue-based-products-hctps.

Authority: 21 U.S.C. 321(h).

Dated: August 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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