



StemC Biotechnology, Inc.
Attention: Raymond Kelly
U.S. Regulatory Correspondent
3422 Leonardo Lane
New Smyrna Beach, FL 32168

December 21, 2022

Re: BK220767

Trade/Device Name: Lipocube Nano, Liopcube Hybrid I, Lipocube Hybrid II, Centrifuge Container

Regulation Number: 21 CFR 878.5040

Regulation Name: Suction lipoplasty system

Regulatory Class: Class II

Product Code: QKL

Dated: June 20, 2022

Received: September 27, 2022

Dear Mr. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosure: Indications for Use

Indications for Use (CBER/OTAT)

510(k) Number: BK220767

Device Name: Lipocube Nano, Liopcube Hybrid I, Lipocube Hybrid II, Centrifuge Container

Indications for Use: The Lipocube is a disposable device for autologous fat transfer. The Lipocube can be used for concentration and transfer of homogenous adipose tissues with a legally marketed lipoplasty system when the concentrated and homogenous fat tissue is re-injected into the recipient body areas of the same patient autologously.

The Lipocube is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired for aesthetic body contouring.

Neurosurgery/ Gastrointestinal Surgery/ Urological Surgery/ General surgery/ Orthopedic Surgery/ Gynecological Surgery /Thoracic Surgery/ Laparoscopic Surgery/ Arthroscopic Surgery/ Plastic and reconstructive surgery.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Tissues and Advanced Therapies

Office Sign-Off Office of Tissues and Advanced Therapies
510(k): BK220767