October 30, 2025

Cytrellis Biosystems, Inc.
Robert Hinz
Vice President, Operations
34 Commerce Way
Woburn, Massachusetts 01801

Re: K252752
Trade/Device Name: ellacor System with Micro-Coring Technology
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: August 26, 2025
Received: August 29, 2025

Dear Robert Hinz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Wilmarie Flores -S Digitally signed by Wilmarie Flores -S

For Jodie Giordano, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252752

Device Name
ellacor Sytem with Micro-Coring Technology

Indications for Use *(Describe)*
The ellacor System with Micro-Coring Technology is indicated for use by medical professionals for the treatment of moderate and severe wrinkles in the mid and lower face in adults aged 22 years or older with Fitzpatrick skin types I-IV. It is further indicated for Fractional Skin Resurfacing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Submitter: Cytrellis BioSystems, Inc.
34 Commerce Way
Woburn, MA 01801

Contact Person: Robert Hinz
V.P., Operation
Phone: 781.689.3149
Email: rhinz@cytrellis.com

Date Prepared : October 30, 2025

Device Trade Name: ellacor System with Micro-Coring Technology

Common Name: Powered Microneedle Device

Classification Name: Microneedling device for aesthetic use

Regulation Number: 21 CFR 878.4430 (Product Code: QAI)

Predicate Device : Cytrellis® Dermal Micro-Coring™ System Device K202517

Device Description:

The ellacor System with Micro-Coring Technology removes unwanted skin by rapidly excising full thickness micro-columns of the dermal and epidermal tissue via specially designed hollow coring needles. The needles are controlled to precise coring depths and positions by the device console and handpiece. The system provides a range of skin removal percentages (treatment densities) and needle depths settings to customize the user needs that is controlled by the LCD touch display on the console. The treatment is applied in 1cm^2 areas of the skin at a time by the handpiece, which has a vacuum assisted disposable in order to help with alignment between treatment areas. The ellacor System with Micro-Coring Technology mechanically removes full thickness sections of skin without evidence of scarring or need for surgical procedure. As much as 7.9% of the surface area of the skin is removed in columns that are the size of the inner diameter of the needle which is too small to cause visible scarring. The holes quickly close because of the natural elastin of the skin as they start to heal. This wound response, combined with the mechanical removal of the skin's surface area, leads to a reduction in the appearance of wrinkles.

Intended Use and Indications for Use:

The ellacor System with Micro-Coring Technology is indicated for use by medical professionals for the treatment of moderate and severe wrinkles in the mid and lower face in adults aged 22 years or older with Fitzpatrick skin types I-IV. It is further indicated for Fractional Skin Resurfacing.

Comparison of Technological Characteristics with the Predicate Device:

Characteristics	ellacor® System with Micro-Coring Technology (Proposed – *K pending*)	Cytrellis Dermal Micro-Coring System (K202517) (Predicate)	AI.ME System (K221011) (Reference)	Comparison to Predicate/Reference and Discussion
Product Code	QAI	QAI	QAI	Identical
Classification Name	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Identical
Device Classification	Class II	Class II	Class II	Identical
Intended Location of Use	Mid and Lower Face Skin Resurfacing	Mid and Lower Face	Any where	The proposed device's intended location of use is the same as that of the predicate and reference devices.
Intended Use and Indications for Use	The ellacor® System with Micro-Coring Technology is intended for the treatment of moderate and severe wrinkles in the mid and lower face. The ellacor® System with Micro-Coring Technology is indicated for use by medical professionals for the treatment of moderate and severe wrinkles in the mid and lower face in	The Cytrellis® Dermal Micro-Coring™ System is intended for the treatment of moderate and severe wrinkles in the mid and lower face. The Cytrellis Dermal Micro-Coring System is indicated for use by medical professionals for the treatment of moderate and severe wrinkles in the mid and lower	The AI.ME system is indicated for fractional skin resurfacing.	The proposed device's intended use and indications for use are the same as that of the predicate and reference devices.

Characteristics	ellacor® System with Micro-Coring Technology (Proposed – *K pending*)	Cytrellis Dermal Micro-Coring System (K202517) (Predicate)	AI.ME System (K221011) (Reference)	Comparison to Predicate/Reference and Discussion
	adults aged 22 years or older with Fitzpatrick skin types I-IV. It is further indicated for Fractional Skin Resurfacing.	face in adults aged 22 years or older with Fitzpatrick skin types I-IV		
Geometry	Single (1) or three (3) needles arranged in a straight line. Needles are ground to 15-degree tip angle resulting in three (3) cutting surfaces and three (3) tips.	Single (1) or three (3) needles arranged in a straight line. Needles are ground to 10-degree tip angle resulting in two (2) cutting surfaces and two (2) tips.	6 hollow needles, hexagon arrangement	The proposed device's needle geometry is within the predicate, and it is supported in the safety study and does not raise new concerns for safety and effectiveness.
Maximum needle penetration (maximum needle length)	Up to 4.0mm core depth setting or 5mm needle tip depth	Up to 4.0mm core depth setting or 5mm needle tip depth	Fixed 3mm core depth	Identical
Needle protrusion setting	0-4.0mm core depth setting or 1- 5mm needle tip depth	0-4.0mm core depth setting or 1- 5mm needle tip depth	Fixed 3mm core depth	Identical
Frequency	8-12 Hz	8-12 Hz	Unknown	Identical

Summary of performance testing:

To demonstrate safety and effectiveness and support substantial equivalence, the ellacor System with Micro-Coring Technology has undergone non-clinical performance testing in line with recognized standards.

(1) The technical specifications and needle characteristics have been identified, including needle length, geometry, maximum penetration depth, and puncture rate.		
(2) Non-clinical performance data demonstrates that the device performs as intended under anticipated conditions of use. The following performance characteristics have been tested:		
(i)	Accuracy of needle penetration depth and puncture rate	Accuracy of needle penetration depth and puncture rate was tested in a suitable skin substrate model and measured using the Keyence Laser System
(ii)	Safety features built into the device to protect against cross-contamination & fluid ingress protection	The device design prevents cross contamination including fluid ingress protection due to the needle cartridge design. Design elements include RFID to prevent needle cartridge re-use and tortuous path for fluid ingress. Testing was performed under worst case scenarios.
(iii)	Identification of the max safe needle penetration depth for the device & for the labeled indications for use	Maximum safe needle penetration depth was identified in a suitable skin substrate model and measured using the Keyence Laser System. Note: Do not treat areas where critical structures may be less than 4mm below the skin surface.
(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.		Performance data demonstrates the sterility of the patient-contacting components of the device according to ISO 11137-1:2006, ISO 11137-2:2013 and ISO/TS 13004:2013
(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.		Performance data supports the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life according to ASTM F1980 -16, ISO 11607-1, ASTM F88-15, ASTM F1140 / F1140M-13, ASTM F2096-11, ASTM F1886 / F1886M-16
(5) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device.		Performance data demonstrates the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device according to IEC 60601-1:2012 3.1 edition and IEC 60601-1-2:2014
(6) Software verification, validation, and hazard analysis must be performed for all software components of the device.		Software verification, validation, and hazard analysis were performed for all software components of the device according to in accordance with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

(7) The patient-contacting components of the device must be demonstrated to be biocompatible.	The patient-contacting components of the device were demonstrated to be biocompatible including evaluation of cytotoxicity, irritation, and sensitization, acute systemic toxicity and material-mediated pyrogenicity and hemocompatibility per ISO 10993-1
(8) Performance data must validate the cleaning and disinfection instructions for reusable components of the device.	A cleaning and disinfection validation was performed for reusable components of the device per AAMI TIR30:2011/(R)2016 and AAMI TIR12:2010
(9) Labeling includes the following:	
(i)	Information on how to operate the device and its components and the typical course of treatment;
(ii)	A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and puncture rate;
(iii)	Validated methods and instructions for reprocessing of any reusable components;
(iv)	Disposal instructions; and
(v)	A shelf life
(10) Patient labeling includes:	
(i)	Information on how the device operates and the typical course of treatment;
(ii)	The probable risks and benefits associated with use of the device;
(iii)	Postoperative care instructions.

Summary of Clinical testing:

A single center, prospective histology study was conducted evaluate the safety and histological effect on tissue using the ellacor Micro-Coring procedure in patients undergoing abdominoplasty The study included three subjects treated a single time at 4mm at a minimum of 3 treatment areas to evaluate safety of the varying treatment depths. A non-treated control area was also designated. Cohort 1 subjects were followed for safety assessments at 7, 14, 21 and 30 days post treatment with histology evaluations for all treatment areas and the control area occurring 30 days after treatment (Day 30).

There is no evidence of trauma, significant inflammation, or hemorrhage. Normal dermis and adipose tissue structures are seen in all histology samples. The results of this study establish the safety of the ellacor Micro-Coring procedure at densities up to 10% and at a depth of up to 4mm, showing complete epithelialization by day-3.

Conclusion:

As described in the comparison tables above, the ellacor® System with Micro-Coring Technology subject device has same intended use and indications for use, similar technological characteristics, and same principles of operation as its predicate and reference device. The technological differences between ellacor

and the predicate/reference device do not raise any new issues of safety and effectiveness. The ellacor® System with Micro-Coring Technology is substantially equivalent to the previously cleared device.