October 13, 2023

InMode Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K231495
Trade/Device Name: The Evolve System with the Transform Applicator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 12, 2023
Received: September 12, 2023

Dear Janice Hogan:

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.

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.10.13 15:16:56 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*

Device Name

The Evolve System with the Transform Applicator

Indications for Use *(Describe)*

The Evolve System with the Transform Applicator employs RF technology and EMS-TENS technology for the treatment of selected medical conditions.

The Transform Applicator in RF mode is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The Transform Applicator in EMS mode is intended for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

The Transform Applicator in TENS mode is intended for:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma acute pain

Additionally the Transform Applicator in sequential RF/EMS mode is intended for:

- Non-invasive lipolysis (breakdown of fat) of the abdomen.
- Reduction in circumference of the abdomen

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.

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510(k) SUMMARY

InMode's Evolve System with the Transform Applicator

Submitter

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Contact Person: Suhair Francis-Najjar
Date Prepared: May 14, 2023

Name of Device: The Evolve System with the Transform Applicator

Common or Usual Name: Electrosurgical, Cutting & Coagulation Device & Accessories

Classification Name: 21 CFR 878.4400 Electrosurgical, Cutting & Coagulation Device & Accessories

Regulatory Class: Class II

Product Code: GEI

Predicate Devices

K202199 BTL-899ST
K163415 Syneron Medical's SlimShape System

Reference Devices

K210877 Inmode's Evolve System with T3 Applicator

Device Description

The Evolve System with the Transform Applicator is designed to deliver non-thermal RF energy and electro-muscle and transcutaneous nerve stimulation for the treatment of different body areas for various medical applications. The Evolve System software controls and regulate the different applied energies in accordance with the user system preprograming and treatment settings. The subject device platform system is identical to the FDA-cleared Evolve System platform (K210877).

The Evolve System includes the following components:

- LCD display touch screen,
- Audio loudspeaker,
- 48V AC/DC power supply,
- Real time controller, distributor card and 2 RF generators,
- Fans

The System operates while connected to the Transform Applicator.

The purpose of this submission is to add non-invasive lipolysis (breakdown of fat) of the abdomen and reduction in circumference of the abdomen to the indications.

Intended Use / Indications for Use

The Evolve System with the Transform Applicator employs RF technology and EMS-TENS technology for the treatment of selected medical conditions.

The Transform Applicator in RF mode is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The Transform Applicator in EMS mode is intended for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

The Transform Applicator in TENS mode is intended for:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma acute pain

Additionally the Transform Applicator in sequential RF/EMS mode is intended for:

- Non-invasive lipolysis (breakdown of fat) of the abdomen.
- Reduction in circumference of the abdomen

Summary of Technological Characteristics

The subject of this 510(k) submission is the expansion of indications for use for the Evolve System with the Transform Applicator to include non-invasive lipolysis (breakdown of fat) of the abdomen. There are no physical changes to the device since its clearance in K210877 which includes both bipolar radiofrequency (RF) / Electrical Muscle Stimulation (EMS) treatment modes. There have been minor software changes to allow the delivery of a sequential RF/EMS for non-invasive lipolysis treatment. Importantly, the parameters of the

delivered RF or EMS pulse are unchanged, the only change is that the treatments are automatically delivered sequentially.

With respect to the proposed additional indication (non-invasive lipolysis of the abdomen; reduction in circumference of the abdomen), the Evolve System with the Transform Applicator is substantially equivalent to the primary predicate device BTL-899ST (K202199) by BTL and the additional predicate device, SlimShape System (K163415) by Syneron Medical. BTL-899ST is selected as primary predicate, as it similarly supplies RF/EMS to achieve non-invasive lipolysis. SlimShape (K163415) is selected as an additional predicate as its RF treatment parameters closely resemble those used by the subject device. The system is also physically identical to the reference device, Evolve System with T3 Applicator cleared in K210877 (aside from minor software changes). A substantial equivalence chart comparing the similarities and differences between the Transform System and its predicate devices is provided below. None of the minor differences in technological features from the predicates raise any new safety or effectiveness questions, and clinical data confirms that these differences do not adversely impact safety or effectiveness.

Performance Data

Updated software documentation was supplied to support the minimal changes to software.

A prospective, multi-site, single arm clinical study of 44 subjects was completed to demonstrate safety and efficacy of the Evolve System with Transform Applicators in circumference reduction. Treatments of sequential bi-polar RF energy and EMS were performed in 3 sessions, two weeks apart from each other. Patients were evaluated at baseline (pre-treatment) and at follow-up visits at 1 and 3 months post-treatment.

Three distinct measurements were used to evaluate fat reduction: circumference measurement by measurement tape (primary endpoint), fat thickness caliper measurement, and fat layer ultrasound measurement. Each of these measures independently demonstrated reduction in fat, and findings were consistent and strongly correlated with each other.

Before and after 3 months photographs were assessed by three blinded evaluators. The success criteria for the percentage of subjects were met, with the correct identification rate exceeding 70%. Subjects rated comfort during treatment using the Therapy Comfort Questionnaire immediately after each of their three treatments. The average comfort scores for each timepoint were rated as between comfortable and indifferent during treatment. Comfort scores statistically significantly improved when comparing the initial and later treatments, suggesting that subjects either acclimated to the treatment over time or that subsequent treatments are less uncomfortable. The majority of subjects were satisfied with the results.

No serious adverse events were observed.

Overall, the findings of this study provide strong evidence for the safety and effectiveness of the system.

Conclusions

The Evolve System with the Transform Applicator is as safe and effective as the predicate devices. The Evolve System with the Transform Applicator has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Evolve System with the Transform Applicator and its predicate devices raise no new issues of safety or effectiveness. Clinical data demonstrate that the Evolve System with the Transform Applicator is as safe and effective as the predicates. Thus, the Evolve System with the Transform Applicator is substantially equivalent.

InMode's Transform System Substantial Equivalence Chart

Full name and 510(k) number	**The Evolve System with the Transform Applicator**	**The SlimShape System** **K163415**	**BTL-899ST** **K202199**	**Comparison**
Device Class	II	II	II	Same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Product Code	GEI	GEI	GEI	Same
Intended Use/ Indications for Use	The Transform Applicator in sequential RF/EMS mode is intended for: • for non-invasive lipolysis (breakdown of fat) of the abdomen. • for reduction in circumference of the abdomen.	The SlimShape System is indicated for non-invasive lipolysis (breakdown of fat) of the abdomen. The device is indicated for reduction in circumference of the abdomen.	BTL-899ST is indicated to be used for: • Non-invasive lipolysis (breakdown of fat) of the abdomen. • Reduction in circumference of the abdomen. • Non-invasive lipolysis (breakdown of fat) of the thighs. • Reduction in circumference of the thighs.	Same intended use. Same indications as SlimShape. Same indications as a subset of the indications of the BTL.
User Population (Skin Type)	No restrictions in skin type	No restrictions in skin type	BTL-899ST is intended for use with Skin Type I, II and III.	BTL is not indicated for use in Skin Types darker than III. This limitation of the predicate is due to technological factors, and any risks are mitigated in the subject device.

Full name and 510(k) number	The Evolve System with the Transform Applicator	The SlimShape System K163415	BTL-899ST K202199	Comparison
System Components	• Energy generators, • Applicators, • Computer for controlling the system's output • System console (touch screen)	• Energy generators, • Applicators, • Computer for controlling the system's output • System console (touch screen)	• Energy generators, • Applicators, • Computer for controlling the system's output • System console (touch screen)	Same
Applicator Design	Hand-free applicators fixed by a fixation belt	Hand-free applicators fixed by a fixation belt	Hand-free applicators fixed by a fixation belt	Same
Selection of Parameters (Intensity, Time) by the User	Yes	Yes	Yes	Same
Principles of Operation	User applies desired variable amounts of energy to the patient until the tissue is heated, while monitoring the degree of heating and any adverse reaction on the patient's skin.	User applies desired variable amounts of energy to the patient until the tissue is heated, while monitoring the degree of heating and any adverse reaction on the patient's skin.	User applies desired variable amounts of energy to the patient until the tissue is heated, while monitoring the degree of heating and any adverse reaction on the patient's skin.	Same
Skin Temperature Monitoring	Yes	Yes	Yes	Same
STOP Button for Patient	Yes	Yes	Yes	Same
Basic Technology	The system combines bipolar radiofrequency with electric muscle stimulation	The system combines bipolar radiofrequency with mechanical suction.	The system combines bipolar radiofrequency with electric muscle stimulation	• All systems are based on bipolar RF energy delivery. • The additional energy applied is different in SlimShape (vacuum; the absence of this feature in the subject device does not raise any new risks). • The application of EMS in the subject device is similar to BTL. In addition, safety is supported by clinical studies.
Sterility	Not Sterile	Not Sterile	Not Sterile	Similar
Single/Multiple Use	Multiple use	Multiple use	Multiple use	Similar