June 10, 2025

EndyMed Medical Ltd.
Ohad Fisher
Regulatory Director
12 Leshem Street
Caesarea, 3088900
Israel

Re: K242996
Trade/Device Name: EndyMed PRO MAX
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OUH, GEI, PBX
Dated: May 6, 2025
Received: May 7, 2025

Dear Ohad Fisher:

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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.06.10 12:52:56 -04'00'

James Jang, Ph.D.
Acting Assistant Director
DHT4A: Division of General 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242996

Device Name
EndyMed PRO MAX

Indications for Use *(Describe)*
The PRO MAX system is a Radiofrequency device intended for use in dermatologic procedures with separate indications for each handpiece.

The TC Handpieces (Shaper Max, Mini Shaper Max, iFine Max) are intended for:
• Relief of minor muscle aches and pain, relief of muscle spasm
• Temporary improvement of local blood circulation

When used up to 65W, the Mini Shaper Max and Small Max handpieces are also intended for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

The FSR Max Handpiece is intended for dermatological procedures requiring ablation and resurfacing of the skin.

The Intensif MAX Handpiece is intended for use in dermatologic procedures for electrocoagulation and hemostasis.

The EndyMed Contour MAX Handpiece is intended for the treatment of the following medical conditions; using the Contour MAX applicator for delivery of non-thermal RF combined with massage:
• Relief of minor muscle aches and pain, relief of muscle spasm
• Temporary improvement of local blood circulation
• Temporary reduction in the appearance of cellulite

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.

510(K) Summary
EndyMed PRO MAX
K242996

Applicant	EndyMed Medical Ltd.
Address	12 Leshem Street Caesarea, Israel 3088900
Contact Person	Ohad Fisher, Regulatory Director
Contact Information	ohadf@endymed.com
Preparation Date	June 08, 2025
Device Trade Name	EndyMed PRO MAX K242996
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number	878.4400
Product Code	GEI, OUH, PBX
Regulatory Class	II
Legally Marketed Predicate/Reference Devices	Imagine TC Skin Therapy System (K083461) Intensif Applicator (K130501) EndyMed Contour Handpiece (K161199) EndyMed FSR Applicator (K101510)

Device Description:
ENDYMED PRO™ MAX is a computerized system that generates pulses of radio frequency (RF) energy that are emitted onto patient skin. The device consists of a console and seven handpieces that emit either ablative or non-ablative radiofrequency.

Indications for use:

The PRO MAX system is a Radiofrequency device intended for use in dermatologic procedures with separate indications for each handpiece.

The TC Handpieces (Shaper Max, Mini Shaper Max, iFine Max) are intended for:
• Relief of minor muscle aches and pain, relief of muscle spasm
• Temporary improvement of local blood circulation
When used up to 65W, the Mini Shaper Max and Small Max handpieces are also intended for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

The FSR Max Handpiece is intended for dermatological procedures requiring ablation and resurfacing of the skin.

The Intensif MAX Handpiece is intended for use in dermatologic procedures for electrocoagulation and hemostasis.

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EndyMed PRO MAX
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The EndyMed Contour MAX Handpiece is intended for the treatment of the following medical conditions; using the Contour MAX applicator for delivery of non-thermal RF combined with massage:

- *Relief of minor muscle aches and pain, relief of muscle spasm*
- *Temporary improvement of local blood circulation*
- *Temporary reduction in the appearance of cellulite*

510(K) Summary
EndyMed PRO MAX
K242996

Substantial Equivalence—Indications for use and Technical Comparison

Predicate and Reference device table by Applicator

Handpiece	Status	Predicate Name	Primary Predicate	Secondary Predicate
Shaper Max	Modified	Imagine TC Skin Therapy System	K083461	K161199- Contour Handpiece
Small Max	Unchanged	Imagine TC Skin Therapy System	K083461	K161199- Contour Handpiece
iFine Max	New	Imagine TC Skin Therapy System	K083461	K161199- Contour Handpiece
Mini Shaper Max	New	Imagine TC Skin Therapy System	K083461	K161199 - Contour Handpiece
Contour Max	Modified	Endymed Contour Handpiece	K161199	N/A
Intensif Max	Unchanged	Intensif Applicator	K130501	N/A
FSR Max	Unchanged	FSR Applicator	K101510	N/A

Indications for Use and Technical Specifications Comparison

EndyMed ProMax System Comparison				
Specification	**Subject Device**	**Predicate: Imagine TC Skin Therapy System**	**Predicate: Contour Handpiece**	**Comparison**
Mode of operation	Bipolar radiofrequency	Bipolar radiofrequency	Bipolar radiofrequency	same
Input Power	110-120VAC, 50/60Hz, 2.7A or 220-240VAC, 50/60Hz, 1.3A	110-120VAC, 50/60Hz, 2.7A or 220-240VAC, 50/60Hz, 1.3A	110-120VAC, 50/60Hz, 2.7A or 220-240VAC, 50/60Hz, 1.3A	Same

Max output power	100W	65W	85W	The new generation of the device has a higher max power output than previous generations, but treatment temperature remains the same.
Console Cooling System	Fans Cooling system	Water cooling system	Water cooling system	different
Thermal Camera (optional)	Supported	Unsupported	unsupported	different

Intensif Max Handpiece Predicate Comparison			
Specification	**Subject Device (Intensif Max)**	**Predicate Device (Intesif handpiece, K130501)**	**Comparison**
Indications for use	The Intensif Max Handpiece is intended for use in dermatologic procedures for electrocoagulation and hemostasis.	The Intensif Applicator is intended for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.	The subject device removes the term “general surgical” to better align with the intended use of the device.
Mode of Action	RF Microneedle	RF microneedle	Same
Frequency	1MHz	1MHz	Same
Mode	Pulsed	Pulsed	Same
Number of needles	25	25	Same
Needle type	**Hyper**: Non-insulated	Non-insulated	Same
Needle Diameter	300 microns	300 microns	same
Max treatment depth	3.5mm	3.5mm	Same
Max power output	25W	25W	Same
Total RF Energy	Up to 62 mJ/pin	Up to 62 mJ/pin	
Pulse Duration	20-170 msec	20-170 msec	

Duty Cycle	50%	50%	Same
Patient Contacting Materials	Biocompatible	Biocompatible	Same

iFine Max Handpiece Predicate Comparison				
Specification	**Subject Device**	**Primary Predicate (Imagine TC)**	**Secondary Predicate (Contour Handpiece)**	**Comparison**
Indications for use	The PRO MAX system is a Radiofrequency device intended for use in dermatologic procedures with separate indications for each handpiece. The iFine Max Handpiece is intended for • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation	The Imagine TC Skin Treatment System is a noninvasive device intended for use in Dermatologic and General Surgical procedures for the noninvasive treatment of mild to moderate facial wrinkles and rhytides.	The EndyMed Contour Max Handpiece is intended for the treatment of the following medical conditions; using the Contour applicator for delivery of non-thermal RF combined with massage: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite.	The subject device excludes the term 'general surgical' to better align with the intended use of the device. The Contour Handpiece predicate is cleared for use with the TC Imagine system. The new and modified handpieces share the pain relief indication for use that the Contour Handpiece is cleared for. They do not, however, include the vacuum function, and therefore do not include the cellulite reduction indication.

510(K) Summary
EndyMed PRO MAX
K242996

Mode of Action	Non-invasive Radiofrequency	Non-invasive Radiofrequency	Non-invasive Radiofrequency with vacuum	Subject device does not include vacuum function
Polarity	Bipolar	Bipolar	Bipolar	Same
Mode	Continuous	Continuous	Continuous	Same
Max output power	Up to 6W	Up to 65W	Up to 85W	The power output of the iFine handpiece is lower than the predicate device, but Tissue Heating Testing with FLIR camera demonstrates the handpiece can meet performance requirements for the pain relief indication.
Vacuum Specifications	**N/A**	**N/A**	**Vacuum Pulse:** **Frequency:** 2.5 Hz **Vacuum Pressure**: >250 mbar, 1-5 level	The subject device does not include the vacuum function and therefore does not include the cellulite reduction indication.
Electrode Size	69.6 mm^2	304.8 mm2 (Small HP)	1381.2 mm^2	Different. Tissue Heating Testing with FLIR camera demonstrates the handpiece can meet performance requirements for the pain relief indication.
Power Density	0.086 W/mm^2	0.21 W/ mm2	0.06 W/ mm^2	Different. Tissue Heating Testing with FLIR camera demonstrates the handpiece can meet performance requirements for the pain relief indication.
Patient Contacting materials	Biocompatible	Biocompatible	Biocompatible	All handpieces have been tested and determined to be biocompatible.

Contour Max Handpiece Predicate Comparison			
Specification	**Subject Device (Contour Max)**	**Predicate Device (Contour Handpiece K161199)**	**Comparison**
Indications for Use	The EndyMed Contour Max Handpiece is intended for the treatment of the following medical conditions; using the Contour applicator for delivery of non-thermal RF combined with massage: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite.	The EndyMed Contour Handpiece is intended for the treatment of the following medical conditions; using the Contour applicator for delivery of non-thermal RF combined with massage: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite.	Same
Mode of Action	Non-invasive Radiofrequency with Vacuum	Non-invasive Radiofrequency with Vacuum	Same
Polarity	Bipolar	Bipolar	Same
Frequency	1Mhz	1MHz	Same
Mode	Continuous	Continuous	Same
Max output power	Up to 100W	Up to 85W	The max output power of the Contour MAX device has increased by 15% from the predicate Contour handpiece from 85W to 100W. Tissue Heating Testing with FLIR camera demonstrates the handpiece can meet performance requirements for the pain relief indication. See details on testing below.
Pulse Duration	30 sec	30 sec	Same

Electrode Size	1381.2 mm^2	1381.2 mm^2	Same
Power Density	0.07 W/mm^2	0.06 W/mm^2	Same
Vacuum Pulse frequency	2.5Hz	2.5Hz	Same
Vacuum Pressure	>250 mbar, 1-5 level	>250 mbar, 1-5 level	Same
Patient Contacting Materials	Biocompatible	Biocompatible	All handpieces have been tested and determined to be biocompatible.

Shaper Max Handpiece Predicate Comparison				
Specification	**Subject Device**	**Primary Predicate**	**Secondary Predicate**	**Comparison**
Indications for use	The Shaper MAX Handpiece is Indicated for • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation	The Imagine TC Skin Treatment System is a noninvasive device intended for use in Dermatologic and General Surgical procedures for the noninvasive treatment of mild to moderate facial wrinkles and rhytides.	The EndyMed Contour Handpiece is intended for the treatment of the following medical conditions; using the Contour applicator for delivery of non-thermal RF combined with massage: • Relief of minor muscle aches and pain, relief of muscle spasm	The subject device excludes the term 'general surgical' to better align with the intended use of the device. The Contour Handpiece predicate is cleared for use with the TC Imagine system. The new and modified handpieces share the pain relief indication for use that the Contour Handpiece is cleared for. They do not, however, include the vacuum function,

			• Temporary improvement of local blood circulation Temporary reduction in the appearance of cellulite.	and therefore do not include the cellulite reduction indication.
Mode of Action	Non-invasive Radiofrequency	Non-invasive Radiofrequency	Non-invasive Radiofrequency with vacuum	Subject does not include vacuum function, and therefore does not include cellulite reduction indication
Polarity	Bipolar	Bipolar	Bipolar	same
Frequency	1MHz	1MHz	1MHz	Same
Mode	Continuous	Continuous	Continuous	same
Max Output Power	Up to 100W	Up to 65W	Up to 85W	Compared to the predicate Large HP, the electrode contact surface area ratio is 2.3 times bigger and the max output power is 1.5 times bigger. Because of this, the power density of the handpiece is the same as the predicate. Tissue Heating Testing with FLIR camera supports the addition of the pain relief indication that is also cleared for the TC Imagine System (Contour Handpiece). The specifications of the Shaper Max Handpiece are similar to the Contour handpiece. The output power is slightly lower, and the vacuum feature is not included in the Shaper Max handpiece.
Pulse Duration	30 sec	30 sec	30 sec	Same.
Electrode Surface Area	1971.1 mm^2	855.6 mm^2	1381.2 mm2	Different. Differences do not present additional risks to safety or efficacy.

				Performance testing demonstrates that the handpieces can perform equivalently.
Vacuum Specifications	N/A	N/A	**Vacuum Pulse: Frequency:** 2.5 Hz **Vacuum Pressure:** >250 mbar, 1-5 level	The Vacuum function is not included with the shaper Max handpiece. The vacuum function is used for cellulite treatment and is not related to pain relief indication.
Power Density	0.05 W/mm2	0.08 W/mm2	0.06 W/mm^2	Similar. Differences do not present additional risks to safety or efficacy.
Patient Contacting Materials	Biocompatible	Biocompatible	Biocompatible	All handpieces have been tested and determined to be biocompatible.

Mini-Shaper Max Handpiece Predicate Comparison				
Specification	**Subject Device**	**Primary Predicate – Imagine TC SMALL handpiece**	**Secondary Predicate**	**Comparison**
Indications for use	The Mini-Shaper MAX Handpiece is Indicated for • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation	The Imagine TC Skin Treatment System is a noninvasive device intended for use in Dermatologic and General Surgical procedures for the noninvasive treatment of mild to moderate facial wrinkles and rhytides.	The EndyMed Contour Handpiece is intended for the treatment of the following medical conditions; using the Contour applicator for delivery of non-thermal RF combined with massage:	The subject device excludes the term 'general surgical' to better align with the intended use of the device. The new and modified handpieces include the wrinkles indication for use, but limit it to 65W power, the same that the predicate device is cleared for. The Contour Handpiece predicate is cleared for use with the TC Imagine

	When used up to 65W, the Mini-Shaper Max handpiece is intended for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.		Relief of minor muscle aches and pain, relief of muscle spasm Temporary improvement of local blood circulation Temporary reduction in the appearance of cellulite.	system. The new and modified handpieces share the pain relief indication for use that the Contour Handpiece is cleared for. They do not, however, include the vacuum function, and therefore do not include the cellulite reduction indication.
Mode of Action	Non-invasive Radiofrequency	Non-invasive Radiofrequency	Non-invasive Radiofrequency with vacuum	Subject does not include vacuum function, and therefore does not include cellulite reduction indication
Polarity	Bipolar	Bipolar	Bipolar	Same
Frequency	1MHz	1MHz	1MHz	Same
Mode	Continuous	Continuous	Continuous	Same
Max Output Power	Up to 70W	Up to 65W	Up to 85W	Compared to the predicate Small HP, in the Mini Shaper MAX HP, the electrode contact surface area ratio is 2.1 times bigger and the max output power is 1.17 times bigger. The power density for the Mini Shaper is lower than the predicate device, making the new handpiece safer than the previously cleared Small Handpiece. The wrinkles indication is limited to 65W to match the predicate. Tissue Heating Testing with FLIR camera supports the addition of the pain relief indication that is also cleared for the TC Imagine System (Contour Handpiece). The

				specifications of the Mini Shaper Max Handpiece are similar to the Contour handpiece. The output power is slightly lower, and the vacuum feature is not included in the Mini Shaper Max handpiece.
Pulse Duration	30 sec	30 sec	30 sec	Same
Electrode Surface Area	641.7 mm^2	304.8 mm^2 (small Handpiece)	1381.2 mm2	Different. Power densities of the electrodes are similar. Differences do not present additional risks to safety or efficacy.
Vacuum Specifications	N/A	N/A	**Vacuum Pulse:** **Frequency:** 2.5 Hz **Vacuum Pressure:** >250 mbar, 1-5 level	Vacuum function is not included with the Mini Shaper Max handpiece. The vacuum function is used for cellulite treatment and is not related to pain relief indication.
Power Density	0.11 W/mm^2	0.21 W/mm^2	0.06 W/mm^2	Different. Differences do not present additional risks to safety or efficacy. Performance testing demonstrates that the handpieces can perform equivalently.
Patient Contacting Materials	Biocompatible	Biocompatible	Biocompatible	All handpieces have been tested and determined to be biocompatible.

SMALL Max Handpiece Predicate Comparison			
Specification	**Subject Device**	**Primary Predicate – Imagine TC SMALL handpiece**	**Comparison**
Indications for use	The Small MAX Handpiece is intended for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.	The Imagine TC Skin Treatment System is a noninvasive device intended for use in Dermatologic and General Surgical procedures for the noninvasive treatment of mild to moderate facial wrinkles and rhytides.	The subject device excludes the term 'general surgical' to better align with the intended use of the device. The new and modified handpieces include the wrinkles indication for use, but limit it to 65W power, the same that the predicate device is cleared for. The Small Max handpiece is identical to the cleared Small handpiece and has the same indication.
Mode of Action	Non-invasive Radiofrequency	Non-invasive Radiofrequency	Same
Polarity	Bipolar	Bipolar	Same
Frequency	1MHz	1MHz	Same
Mode	Continuous	Continuous	same
Max Output Power	Up to 60W	Up to 65W	Same as Imagine TC Small handpiece
Pulse Duration	30 sec	30 sec	Same
Electrode Surface Area	304.8 mm^2	304.8 mm^2 (small Handpiece)	Same as Imagine TC Small Handpiece
Vacuum Specifications	N/A	N/A	
Power Density	0.21 W/mm^2	0.21 W/mm^2	Same as Imagine TC Small Handpiece, higher power density than Contour Max due to smaller electrode size.

Patient Contacting Materials	**Electrode:** Copper plated with hard Chrome *or* ST-316 **Handpiece:** PC Makrolon 2458 or Tritan Copolyester MXF121	**Electrode:** ST-316 **Handpiece:** Steralloy #2463	ST-316 electrodes are the same as the predicate device. Biocompatibility testing (Sensitization, Irritation, Cytotoxicity) was conducted on handpieces with both stainless steel and copper coated electrodes.

FSR MAX Handpiece Predicate Comparison			
Specification	**Subject (FSR Max handpiece)**	**Predicate Device (FSR Handpiece** K101510**)**	**Comparison**
Indications for Use	The FSR MAX Handpiece is intended for dermatological procedures requiring ablation and resurfacing of the skin.	The FSR MAX Applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin.	Same
Mode of Action	Ablative Radiofrequency	Ablative Radiofrequency	Same
Polarity	Bipolar	Bipolar	Same
Frequency	1MHz	1MHz	Same
Mode	pulsed	pulsed	Same
Max output power	1-6W	1-6W	Same
Pulse duration	10-60 msec	10-60 msec	Same
Electrode Size	0.07 mm^2	0.07 mm^2	Same
Power density	84.8 W/mm^2	84.8 W/mm^2	Same
Patient Contacting Materials	Biocompatible	Biocompatible	Same

Performance Testing

Verification and validation activities were successfully completed and establish that the EndyMed PRO MAX performs as intended. Testing included the following:

- IEC 60601-1:2005 + A1:2012; Medical Electrical Equipment- Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014; Medical Electrical Equipment- Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- IEC 60601-2-2:2017; Medical Electrical Equipment –part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes
- EN ISO 14971:2012; Medical Devices – Application Of Risk Management To Medical Devices
- ISO 11135 Second edition 2014-07-15: Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical device
- ISO 10993-1:2018: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- ISO 11607-1:2019-02: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)]

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Bench testing was performed to verify the accuracy of the output of RF energy.

Performance Testing - Tissue Heating Testing

The Shaper Max, iFine Max, Mini Shaper Max, and Contour Max handpieces were all subjected to tissue heating testing to verify their safety and effectiveness for the requested pain relief indication. The Small Max Handpiece was not included in the study because it has not been modified since its original clearance. The testing was performed on 3 subjects with 3 anatomical sites each. The test was performed at the device's high settings and demonstrated that each handpiece can maintain a therapeutic temperature of 39-45°C for at least 10 minutes of treatment.

Biocompatibility

A biocompatibility assessment has been conducted to determine the biocompatibility risks of the change in patient contacting materials, and appropriate testing has been conducted to demonstrate safety of these materials.

510(K) Summary
EndyMed PRO MAX
K242996

Discussion

This submission is intended to combine multiple handpieces previously cleared for use into a single system, introduce minor modifications to the system handpieces, and include new handpieces. The EndyMed PRO MAX system is very similar to the previously cleared TC Imagine Skin Treatment System. The differences are in max output power and the addition of a thermal camera for temperature monitoring (optional). The original TC Imagine Skin Treatment System included 2 handpieces. Three additional handpieces have been added with individual 510(k)s over time (Contour Handpiece, Intensif Applicator and FSR Applicator). This submission adds two new handpieces (iFine Max and Mini-shaper Max).

The current generation of handpieces have all been verified for output power control. The increased wattage allows the device to more quickly reach the target temperature of 40-45°C. The new handpieces – iFine Max and Mini Shaper Max are smaller than the previously cleared handpieces, providing opportunities to treat smaller and harder to reach areas. The overall design and principle of operation are the same between devices. Many of the modified handpieces are closest in comparison to the Contour Handpiece (K161199), which was cleared for use with the Imagine TC Skin Therapy System. Therefore, the Contour Handpiece is included as a predicate device as well to establish a pain relief indication. Performance testing described below shows the TC handpieces and Contour Handpiece perform as intended to meet the pain relief indication standards.

The Intensif Max tip is unchanged and is substantially equivalent to the predicate device.