



August 12, 2024

TermoSalud  
% Aubrey Thompson  
Regulatory Consultant  
Hoy & Associates Regulatory Consulting  
1830 Bonnie Way  
Sacramento, California 95825

Re: K241656

Trade/Device Name: Eneka Selectif  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: June 8, 2024  
Received: June 10, 2024

Dear Aubrey Thompson:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA L. HITHE -S  
Digitally signed by  
TANISHA L. HITHE -S  
Date: 2024.08.12  
18:26:08 -04'00'

Tanisha Hithe  
Assistant Director  
DHT4A: Division of General Surgery Devices  
OHT4: Office of Surgical & Infection Control Devices,  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (*if known*)

K241656

Device Name

Eneka Selectif

Indications for Use (*Describe*)

Intended Use

ENEKA SELECTIF is intended for use in dermatologic and general surgical procedures.

Indications for Use

ENEKA SELECTIF System with 755nm Laser applicator is intended for:

- Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment and prevention of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI).
- Treatment of benign pigmented lesions.

ENEKA SELECTIF System with 810nm Laser applicator is intended for:

- Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment and prevention of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI).
- Treatment of benign pigmented lesions.

ENEKA SELECTIF System with 1060nm Laser applicator is intended for:

- Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment and prevention of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI).
- Treatment of benign vascular lesions.

ENEKA SELECTIF System with 810 – 1060nm Laser applicator is intended for:

- Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment and prevention of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI).

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

### ENKA SELECTIF

K241656

This 510(K) Summary of safety and effectiveness for the ENKA SELECTIF is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

|                                   |                                                    |
|-----------------------------------|----------------------------------------------------|
| Applicant                         | TermoSalud                                         |
| Address                           | Ataulfo Frieria Tarfe, 8 - 33211 Gijón, Spain      |
| Contact Person                    | Aubrey Thompson, Regulatory Consultant             |
| Contact Information               | Aubreythompson@hoyregulatory.com                   |
| Preparation Date                  | August 6, 2024                                     |
| Device Trade Name                 | ENKA SELECTIF                                      |
| K Number                          | K241656                                            |
| Common Name                       | Powered Laser Surgical Instrument                  |
| Regulation Number                 | 21 CFR 878.4810                                    |
| Product Code                      | GEX                                                |
| Regulatory Class                  | II                                                 |
| Legally Marketed Predicate Device | Primelase Excellence (K201594), ENKA PRO (K223680) |

#### Device Description:

The ENKA SELECTIF is a non-invasive diode laser system used for hair removal, prevention and treatment of Pseudofolliculitis barbae and treatment of vascular and pigmented lesions.

The system operates at different wavelengths (755, 810 and 1060 nm) separately plus a blended handpiece combining three wavelengths (810, 940 and 1060 nm).

The ENKA SELECTIF is a diode laser device with 7 handpieces (spot sizes 10x9mm, 20x9mm and 30x12mm) and it allows two modes of treatment, DHR and FDHR. Both of them can be applied with every handpiece. Mode DHR allows the configuration of pulse width, frequency and fluency and mode FDHR allows the configuration of frequency and fluency.

This submission is based on substantial equivalence between the Eneka Selectif and its predicate device, the Primelase Excellence diode laser. In addition, this device is an expansion of capabilities for the previously cleared Eneka Pro (K223680), which is used as a reference device. The following tables describe the similarities between the three devices.

#### Intended Use and Indications for Use:

##### Intended Use

ENKA SELECTIF is intended for use in dermatologic and general surgical procedures.

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Indications for Use

ENEKA SELECTIF System with 755nm Laser applicator is intended for:

- Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment and prevention of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI).
- Treatment of benign pigmented lesions.

ENEKA SELECTIF System with 810nm Laser applicator is intended for:

- Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment and prevention of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI).
- Treatment of benign pigmented lesions.

ENEKA SELECTIF System with 1060nm Laser applicator is intended for:

- Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment and prevention of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI).
- Treatment of benign vascular lesions.

ENEKA SELECTIF System with 810 – 1060nm Laser applicator is intended for:

- Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment and prevention of Pseudofolliculitis barbae (PFB).
- Use on all skin types (Fitzpatrick I-VI).

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**Substantial Equivalence—Indications for use comparison:**

| Subject Device: Eneka Selectif                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Predicate Device: Primelase Excellence<br>K201594                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Reference Device: Eneka Pro<br>K223680                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>ENEKA SELECTIF System with 755nm Laser applicator is intended for:</p> <ul style="list-style-type: none"> <li>• Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.</li> <li>• Treatment and prevention of Pseudofolliculitis barbae (PFB).</li> <li>• Use on all skin types (Fitzpatrick I-VI).</li> <li>• Treatment of benign pigmented lesions.</li> </ul> <p>ENEKA SELECTIF System with 810nm Laser applicator is intended for:</p> <ul style="list-style-type: none"> <li>• Hair removal with Dynamic and Fast Dynamic (FDHR) modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.</li> <li>• Treatment and prevention of Pseudofolliculitis barbae (PFB).</li> <li>• Use on all skin types (Fitzpatrick I-VI).</li> </ul> | <p>PRIMELASE Excellence System with 755nm Laser applicator is intended for:</p> <ul style="list-style-type: none"> <li>• Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.</li> <li>• Treatment of Pseudofolliculitis barbae (PFB).</li> <li>• Use on all skin types (Fitzpatrick I-VI).</li> <li>• Treatment of benign pigmented lesions</li> </ul> <p>PRIMELASE Excellence System with 810nm Laser applicator is intended for:</p> <ul style="list-style-type: none"> <li>• Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.</li> <li>• Treatment of Pseudofolliculitis barbae (PFB).</li> <li>• Use on all skin types (Fitzpatrick I-VI).</li> <li>• Treatment of benign pigmented lesions</li> </ul> | <p>Indications for use for Eneka Pro diode laser hair removal system with 808nm applicators include: • Hair Removal with Dynamic (DHR) and Fast Dynamic (FDHR) mode intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. • Treatment of Pseudofolliculitis barbae (PFB). • Use on all skin types (Fitzpatrick I-VI)</p> |

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <ul style="list-style-type: none"> <li>• Treatment of benign pigmented lesions.</li> </ul> <p>ENEKA SELECTIF System with 1060nm Laser applicator is intended for:</p> <ul style="list-style-type: none"> <li>• Hair removal with Dynamic and Fast Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.</li> <li>• Treatment and prevention of Pseudofolliculitis barbae (PFB).</li> <li>• Use on all skin types (Fitzpatrick I-VI).</li> <li>• Treatment of benign vascular lesions.</li> </ul> <p>ENEKA SELECTIF System with 810 – 1060nm Laser applicator is intended for:</p> <ul style="list-style-type: none"> <li>• Hair removal with Dynamic and Fast Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.</li> <li>• Treatment and prevention of Pseudofolliculitis barbae (PFB).</li> <li>• Use on all skin types (Fitzpatrick I-VI).</li> </ul> | <p>PRIMELASE Excellence System with 1060nm Laser applicator is intended for:</p> <ul style="list-style-type: none"> <li>• Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.</li> <li>• Treatment of Pseudofolliculitis barbae (PFB).</li> <li>• Use on all skin types (Fitzpatrick I-VI).</li> <li>• Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, and other benign vascular lesions and leg veins.</li> <li>• Treatment of wrinkles</li> </ul> <p>PRIMELASE Excellence System with 810-1060nm Laser applicator is intended for:</p> <ul style="list-style-type: none"> <li>• Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.</li> <li>• Treatment of Pseudofolliculitis barbae (PFB).</li> <li>• Use on all skin types (Fitzpatrick I-VI).</li> </ul> |  |
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**Substantial Equivalence: Technical Specifications Comparison**

| Specification          | Subject Device<br>ENEKA SELECTIF                                                               | Predicate Device<br>Primelase Excellence –<br>K201594                                                                          | Reference Device ENEKA PRO –<br>K223680                         | Comparison                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Principle of operation | AlGaAs Laser diode array                                                                       | AlGaAs Laser diode array                                                                                                       | AlGaAs Laser diode array                                        | Same                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Laser Wavelength       | 755 nm<br>810 nm<br>1060 nm<br>810-1060 nm                                                     | 755 nm<br>810 nm<br>1060 nm<br>810 – 1060 nm                                                                                   | 808nm                                                           | Same. This submission includes 7 handpieces with 755, 810, 1060nm and 810-1060nm wavelengths. The predicate device contains handpieces with the same wavelengths, including the wavelength with multiple wavelength options. The ENEKA PRO includes 2 handpieces at 808nm, both of which are included in the current submission.                                                                                                                                            |
| Laser Contact          | Sapphire, Al <sub>2</sub> O <sub>3</sub>                                                       | Sapphire, Al <sub>2</sub> O <sub>3</sub>                                                                                       | Sapphire, Al <sub>2</sub> O <sub>3</sub>                        | Same                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Spot Sizes             | 10x9mm (0.9cm <sup>2</sup> ),<br>30x12mm (3.6cm <sup>2</sup> )<br>20x9mm (1.8cm <sup>2</sup> ) | 10x10mm (1.0cm <sup>2</sup> )<br>20x9mm (1.8cm <sup>2</sup> )<br>30x9mm (2.7cm <sup>2</sup> )<br>30x17mm (5.1cm <sup>2</sup> ) | 20x9mm (1.8cm <sup>2</sup> ),<br>34x14mm (4.76cm <sup>2</sup> ) | The spot size for ENEKA SELECTIF L handpiece (10x9mm) is very similar to the spot size of Primelase (10x10mm). The spot size of ENEKA SELECTIF XL handpiece (20x9mm) is identical to Primelase (20x9mm) and Eneka Pro (20x9mm) handpieces. The spot size dimension of the 2XL handpiece for ENEKA SELECTIF (30x12mm) is between the two largest Primelase handpieces (30x9mm and 30x17mm). Safety and effectiveness are not impacted by the minor differences in spot size. |
| Fluence Max            | 100J/cm <sup>2</sup>                                                                           | 120J/cm <sup>2</sup>                                                                                                           | 43J/cm <sup>2</sup>                                             | The fluence of the ENEKA SELECTIF is very similar to the fluence of the predicate device. The difference with                                                                                                                                                                                                                                                                                                                                                               |

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|                          |                                              |                                                   |                                              |                                                                                                                                                                                                                      |
|--------------------------|----------------------------------------------|---------------------------------------------------|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          |                                              |                                                   |                                              | ENEKA PRO is that this device is used only for hair removal and this treatment does not require high fluence values. Fluence for Hair removal treatments with the Eneka Selectif is limited to 43J/cm <sup>2</sup> . |
| Frequency                | 1 – 4Hz (Dynamic)<br>5 – 10Hz (Fast Dynamic) | Up to 3 Hz (Static)<br>5 – 10 Hz (Dynamic)        | 1 – 4Hz (Dynamic)<br>5 – 10Hz (Fast Dynamic) | Same. The frequency of the ENEKA SELECTIF is identical to ENEKA PRO, and is within the range of frequencies of the predicate device.                                                                                 |
| Pulse Duration           | 5 – 400ms                                    | 3 – 400 ms                                        | 5 – 400ms                                    | The pulse duration of ENEKA SELECTIF is identical to the reference device pulse duration and very similar to the predicate's pulse duration.                                                                         |
| Tissue Cooling           | Contact cooling system                       | Contact continuous, thermo—electrical             | Contact cooling system                       | Same.                                                                                                                                                                                                                |
| Cooling Temperature      | 3 °C                                         | 5 °C                                              | 3 °C                                         | Same. The contact cooling temperature is identical to ENEKA PRO predicate device, and almost identical ( $\pm 2$ °C) to Primelase.                                                                                   |
| Contact detection system | Yes                                          | No                                                | No                                           | Different. There are no contact detection systems on the predicate or reference devices. Contact detection system is a requirement to comply with the last revision of IEC 60601-2-22.                               |
| User Interface           | LCD Touchscreen                              | LCD Touchscreen                                   | LCD Touchscreen                              | Same.                                                                                                                                                                                                                |
| Pulsing Control          | Finger Switch                                | Finger Switch                                     | Finger Switch                                | Same.                                                                                                                                                                                                                |
| Configuration            | Main unit and handpiece                      | Main unit, handpiece, and foot control (optional) | Main unit and handpiece                      | Same                                                                                                                                                                                                                 |

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|                      |                                      |                                  |                                      |                                                     |
|----------------------|--------------------------------------|----------------------------------|--------------------------------------|-----------------------------------------------------|
| Laser Classification | Class 1C (Module class 4)            | Class 4                          | Class 4                              | Same.                                               |
| Power Supply         | 115 VAC 50/60 Hz<br>230 VAC 50/60 Hz | Single Phase, 100-240V, 50-60 Hz | 115 VAC 50/60 Hz<br>230 VAC 50/60 Hz | Different from Predicate, same as reference device  |
| Dimension            | 620 x 430 x 630 mm                   | 1140 x 480 x 550 mm              | 620 x 430 x 630                      | Different from Predicate, same as reference device. |
| Weight               | 32 kg                                | 75 kg                            | 32 kg                                | Different from Predicate, same as reference device  |

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**Performance Testing**

Verification and validation activities were successfully completed and establish that the ENEKA SELECTIF performs as intended. Testing included the following:

IEC 60601-1:2005 + A1:2012 + A2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014+A1:2020 Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility Requirements and tests

IEC 60601-2-22:2019 : Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

ISO 10993-1:2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

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

Performance testing was conducted to verify the output power of the laser at each power level with all handpieces.

**Clinical Evidence** – N/A. No clinical studies were conducted as part of this submission.

**Biocompatibility** – The patient contacting materials in the Eneka Selectif are identical to those used in the Eneka Pro. No modifications to materials have been made, and no additional testing was required.

**Conclusion**

Based on the comparison and analysis above, the ENEKA SELECTIF and PRIMELASE are nearly identical in the specifications and the hair removal handpieces and indications are identical to the previously cleared Eneka Pro. The indications for use are identical to the PRIMELASE with the exception of wrinkle treatment, which is not included in this submission. The Eneka Selectif and Primelase have small differences in the design that do not impact the safety or effectiveness of the subject device, but only impact the user experience. To increase the safety of the treatment, the ENEKA SELECTIF includes a contact detection system to avoid firing the laser when no contact with skin is established. The main difference between them resides in their accessories (wavelengths and spot sizes). The Eneka Selectif is lacking one spot size that is included in the predicate device, and the spot size for the Eneka Selectif are slightly different from the Eneka Pro.

The treatment modes only differ in the naming; the modes from Primelase Excellence, Eneka Pro and Eneka Selectif are nearly identical. The Primelase Excellence refers to its lower frequency as "static" and "dynamic." Eneka Selectif and Eneka Pro refer to the lower frequency and "dynamic" and the higher frequency as "fast dynamic." The frequency ranges for the different modes are nearly identical. The devices can be considered substantially equivalent.