



September 24, 2026

BLUECORE COMPANY Co., Ltd.  
Kwon Bu Gyeong  
Official Correspondent  
#402-404,34,Yarl 3-Gil, Mulgeum-Eup  
Yangsan-Si, Gyeonsangnam-Do  
Yangsan, KR 50652  
Republic Of Korea

Re: K254199

Trade/Device Name: PicoreMax (PicoreMax)

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: September 15, 2026

Received: September 15, 2026

Dear Kwon Bu Gyeong:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

Sincerely,

YAN FU-S

Digitally signed by YAN FU -S  
Date: 2026.09.24 19:41:10  
-04'00'

for Tanisha Hithe  
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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254199

?

Please provide the device trade name(s).

?

PicoreMax (PicoreMax)

Please provide your Indications for Use below.

?

The PicoreMax is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology and general plastic surgery as follows.

### Indications for use

#### 532 nm Wavelength

- Indicated for the removal of tattoos for Fitzpatrick skin types I – III to treat the following tattoo colors : red, yellow and orange.
- Indicated for benign pigmented lesions removal for Fitzpatrick skin types I – IV.

(nominal delivered energy of 585 nm and 650 nm with the Optional Dye Laser Handpiece)

- Tattoo removal (light ink: red, sky blue, green)
- Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi
- Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions; including, but not limited to: striae and scars, (excludes the 650nm wavelength)
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)

#### 1064 nm Wavelength:

- Indicated for the removal of tattoos for all skin types (Fitzpatrick skin types I – VI) to treat the following tattoo colors : black, brown, green, blue and purple.
- Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.
- Focus (Fractional) handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I – IV.
- Focus (Fractional) handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II – V.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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**510(k) summary (510(k) #: K254199)**

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

**I. Submitter Information [21 CFR 807.92(a) (1)]**

|                             |                                                                                                                                                                                                                                                              |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Applicant/Manufacturer Name | BLUECORE COMPANY Co., Ltd.                                                                                                                                                                                                                                   |
| Applicant Address           | #402-404, 34, Yari 3-gil, Mulgeum-eup, Yangsan-si, Gyeongsangnam-do, KR 50652, Republic of Korea                                                                                                                                                             |
| Contact Person              | Bu Gyeong Kwon<br>Regulatory Affairs Manager<br><br>Tel.: +82 070 4870 2042<br>Fax: +82 055 366 4319<br><br>E-mail: <a href="mailto:kgb7881@bluecorecompany.com">kgb7881@bluecorecompany.com</a><br><a href="mailto:kgb7881@blccp.com">kgb7881@blccp.com</a> |
| Date Prepared               | July. 27. 2026                                                                                                                                                                                                                                               |

**II. Name of device [21 CFR 807.92 (a) (2)]**

|                     |                                          |
|---------------------|------------------------------------------|
| Device Trade Name   | PicoreMax                                |
| Common Name         | PicoreMax Picosecond Nd:YAG Laser System |
| Classification Name | Power Laser Surgical Instrument          |
| Regulation Number   | 21 CFR 878.4810                          |
| Product Code        | GEX                                      |

**III. Predicate and Reference Devices [21 CFR 807.92(a) (3)]**

|                      |                                                          |
|----------------------|----------------------------------------------------------|
| Predicate #1         | K240983                                                  |
| Predicate Trade Name | Discovery Pico; Discovery Pico Plus; Discovery Pico Derm |
| Product Code         | GEX                                                      |

|                      |                            |
|----------------------|----------------------------|
| Predicate #2         | K160488                    |
| Predicate Trade Name | enlighten III Laser System |
| Product Code         | GEX                        |

|                      |                                        |
|----------------------|----------------------------------------|
| Predicate #3         | K133254                                |
| Predicate Trade Name | RevLite Q-Switched Nd:YAG Laser System |
| Product Code         | GEX                                    |

**IV. Device Description [21 CFR 807.92(a) (4)]**

The subject device, PicoreMax, is a picosecond Nd:YAG laser system that uses Nd:YAG as the laser medium to generate laser beams at wavelengths of 532 nm and 1064 nm.

The user can select from various handpieces. Moreover, specific software controls the device functions and allows the user to select through the touchscreen display.

The system is intended to be used in user facilities such as hospitals, physicians' offices and medical spas, and its major components are the main console unit, foot switch, and individual modules.

The device is re-usable and non-sterile; instructions for cleaning its components between uses are provided in the labeling.

PicoreMax Laser System consists of:

- System console (contains the system software, power supply, and various other electronic and mechanical parts)
- Operator control panel with touch-screen technology (GUI)
- Handpiece (Zoom / Collimated / Recurve S, D, SS, E / Focus 7/ Gold/ Ruby)
- Footswitch and accessories

## **V. Indications for Use [21 CFR 807.92(a) (5)]**

The PicoreMax is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology and general plastic surgery as follows.

### **532 nm**

Indicated for the removal of tattoos for Fitzpatrick skin types I – III to treat the following tattoo colors : red, yellow and orange.

Indicated for benign pigmented lesions removal for Fitzpatrick skin types I – IV.

### **(nominal delivered energy of 585 nm and 650 nm with the Optional Dye Laser Handpiece)**

Tattoo removal (light ink: red, sky blue, green)

Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi

Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis

Skin Resurfacing for Acne Scars and Wrinkles

Benign cutaneous lesions; including, but not limited to: striae and scars, (excludes the 650nm wavelength)

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)

### **1064 nm**

Indicated for the removal of tattoos for all skin types (Fitzpatrick skin types I – VI) to treat the following tattoo colors : black, brown, green, blue and purple.

Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.

Focus (Fractional) handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I – IV.

Focus (Fractional) handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II – V.

**VI. Summary of technological characteristics of the device compared to the predicate [21 CFR 807.92(a)(6)]**

The subject PicoreMax system shares with its predicate devices, Discovery Pico Family (K240983), Enlighten III Laser System (K160488), and RevLite (K133254), the same underlying technology and presents similar technological characteristics. All systems use laser energy delivered to the skin surface via applicators.

|                                   | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name                      | PicoreMax                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Discovery Pico; Discovery Pico Plus; Discovery Pico Derm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 510(k) Number                     | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | K240983                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Manufacturer                      | BLUECORE COMPANY Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Quanta System Spa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Laser Medium                      | Picosecond Nd:YAG                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Picosecond Nd:YAG                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Wavelength                        | 1064 / 532 [nm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 1064 / 532 [nm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Pulse Energy (mJ)                 | 1064 nm: Max.800 [mJ]<br>532 nm: Max. 300 [mJ]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 1064 nm: Max. 800 [mJ]<br>532 nm: Max. 300 [mJ]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Fluence (J/cm <sup>2</sup> )      | 1064 nm:<br>Zoom Handpiece: Max. 5.6 J/cm <sup>2</sup><br>Recurve S Handpiece: Max. 2.2 J/cm <sup>2</sup><br>Recurve D Handpiece: Max. 2.2 J/cm <sup>2</sup><br>Recurve SS Handpiece: Max. 2.2 J/cm <sup>2</sup><br>Collimated Handpiece: Max. 2.1 J/cm <sup>2</sup><br><br>532 nm:<br>Zoom Handpiece: Max. 2.8 J/cm <sup>2</sup><br>Recurve E Handpiece: Max. 1.0 J/cm <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 1064 nm: Max. 5.6 J/cm <sup>2</sup><br>532 nm: Max. 2.8 J/cm <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Pulse Width (Pulse Duration)      | 1064 nm: 450 [ps]<br>532 nm: 380 [ps]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 1064 nm: 450 – 800 [ps]<br>532 nm: 370 – 600 [ps]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Frequency                         | Max.10 [Hz]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Max.10 [Hz]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Spot Size                         | Zoom H/P: 2 – 10 [mm]<br>Collimated H/P: 7 [mm]<br>Recurve (Square): 6 [mm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Round: 2 – 12 [mm]<br>Square: 2,3,4,5,7 [mm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Indication for use                | <p>The PicoreMax is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery as follows.</p> <p>532 nm</p> <ul style="list-style-type: none"> <li>- Indicated for the removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.</li> <li>- Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.</li> </ul> <p>1064 nm</p> <ul style="list-style-type: none"> <li>- Indicated for the removal of tattoos for all skin types (Fitzpatrick skin types I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.</li> <li>- Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.</li> <li>- Focus (Fractional) handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.</li> <li>- Focus (Fractional) handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.</li> </ul> | <p>The Discovery Pico Family is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery as follows.</p> <p>532 nm</p> <ul style="list-style-type: none"> <li>- Indicated for the removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.</li> <li>- Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.</li> <li>- Only with fractional handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.</li> </ul> <p>1064 nm</p> <ul style="list-style-type: none"> <li>- Indicated for the removal of tattoos for all skin types (Fitzpatrick skin types I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.</li> <li>- Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.</li> <li>- Only with fractional handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.</li> </ul> <p>Only with fractional handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.</p> |
| With Fractional handpiece         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Spot overall Dimension            | Focus 7 (mm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Round 8 (mm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Wavelength (nm)                   | 1064                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 1064                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Energy(J) <sub>Max</sub>          | Focus 7: 0.283                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 1064 (ps): 0.73                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Fluence /Dot (J/cm <sup>2</sup> ) | Focus 7: 18.39                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 1064 (ps): 18.4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Dot Diameter (um)                 | Focus 7: 200                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 1064 (ps): 200                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Coverage (%)                      | Focus 7: 4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 1064 (ps): 4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

|                              | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Predicate Device                                                                                                                                                                                                                                                                                                                                            | Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name                 | PicoreMax                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | enlighten III Laser System                                                                                                                                                                                                                                                                                                                                  | RevLite Q-Switched Nd:YAG Laser System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 510(k) Number                | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | K160488                                                                                                                                                                                                                                                                                                                                                     | K133254                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Manufacturer                 | BLUECORE COMPANY Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Cutera, Inc                                                                                                                                                                                                                                                                                                                                                 | Cynosure                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Laser Medium                 | Picosecond Nd:YAG                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Q-switched Nd:YAG laser                                                                                                                                                                                                                                                                                                                                     | Q-switched Nd:YAG laser                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Wavelength                   | 585 / 650 [nm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 670 [nm]                                                                                                                                                                                                                                                                                                                                                    | 532 [nm]<br>585 [nm] (with optional dye handpiece)<br>650 [nm] (with optional dye handpiece)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Pulse Energy (mJ)            | 585 nm: Max.200 [mJ]<br>650 nm: Max. 125 [mJ]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 670 nm: Max. 125 [mJ]                                                                                                                                                                                                                                                                                                                                       | 1.6 J                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Fluence (J/cm <sup>2</sup> ) | 585 nm: Max. 1.02 J/cm <sup>2</sup><br>650 nm: Max. 1.77 J/cm <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 670 nm: Max. 4.0 J/cm <sup>2</sup>                                                                                                                                                                                                                                                                                                                          | 532 nm: Max. 1- 8 J/cm <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Pulse Width (Pulse Duration) | 585 nm / 650 nm: 380 [ps]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 670 nm: 660 [ps]                                                                                                                                                                                                                                                                                                                                            | 532 nm: 7-20 [ns]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                    | Max.2 [Hz]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Max.10 [Hz] or single shot                                                                                                                                                                                                                                                                                                                                  | Max. 10 [Hz] or single shot                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Spot Size                    | 585nm: 5 [mm]<br>650nm: 3 [mm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 670 nm: 2, 3, 4, 5, 6 [mm]                                                                                                                                                                                                                                                                                                                                  | 532 nm: 2 - 8.5 [mm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Indication for use           | <p>The PicoreMax is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.</p> <p>532nm<br/>(nominal delivered energy of 585 nm and 650 nm with the Optional Dye Laser Handpiece)</p> <p>Tattoo removal (light ink: red, sky blue, green)<br/>Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi<br/>Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis<br/>Skin Resurfacing for Acne Scars and Wrinkles<br/>Benign cutaneous lesions; including, but not limited to: striae and scars, (excludes the 650nm wavelength)<br/>Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)</p> | <p>The enlighten III laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.</p> <p>670 nm<br/>The 670 nm wavelength of the enlighten III laser system is indicated for treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III.</p> | <p>The RevLite Q-Switched Nd:YAG Laser System consists of an electrically powered Console, in which laser energy produced within the system is delivered to the tissues by means of an articulated arm, Handpiece Adaptor and specially designed handpiece. The user activates laser emission by means of a footswitch.</p> <p>532 nm<br/>(nominal delivered energy of 585 nm and 650 nm with the Optional Multilite Dye Laser Handpiece)</p> <p>Tattoo removal (light ink: red, sky blue, green)<br/>Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi<br/>Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis<br/>Skin Resurfacing for Acne Scars and Wrinkles<br/>Benign cutaneous lesions; including, but not limited to: striae and scars, (excludes the 650nm wavelength)<br/>Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)</p> |

**VII. Nonclinical Performance Testing [21 CFR 807.92(b)(1)]**

IEC 60601-1 2020-08: Medical Electrical Equipment – Part 1: General Requirements for safety and essential performance

IEC 60601-1-2 2020-09: Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance

IEC 60601-2-22 – 2019-11: Medical Electrical Equipment – Part 2-22 – Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 60825-1, 2007-003: Safety of laser products - Part 1: Equipment classification, and

requirements IEC 10993-5, 2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity IEC 10993-10, 2021 Biological evaluation of medical devices – Part 10: Tests

for skin sensitization IEC 10993-23, 2021 Biological evaluation of medical devices – Part 23:

Tests for irritation

In addition, software verification and validation testing was performed to the requirements of IEC 62304 and biocompatibility conformance to FDA standards was established.

**VIII. Clinical Data [21 CFR 807.92(b) (2)]**

Based on the similarities in the safety and effectiveness profiles of the subject, reference, and primary predicate devices, no animal or clinical studies were deemed needed to support this submission.

**IX. Conclusions Safety and Effectiveness SE [21 CFR 807.92(b) (3)]**

The PicoreMax is as safe and effective as the predicate devices.

The proposed PicoreMax has the same intended use and indications, similar technological characteristics, and the same principle of operation as the predicate devices.

Thus, the PicoreMax is substantially equivalent to the predicate devices.