October 13, 2022

Candela Corporation
Danielle Gibboney
Sr. Regulatory Affairs Specialist
251 Locke Drive
Marlborough, Massachusetts 01752

Re: K220853
Trade/Device Name: PicoWay Laser System
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 8, 2022
Received: September 8, 2022

Dear Danielle Gibboney:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K220853

Device Name
PicoWay Laser System

Indications for Use *(Describe)*
The PicoWay laser system is indicated for the following at the specified wavelength:
• 532 nm: Removal of tattoos for Fitzpatrick Skin Types I-III to treat the following tattoo colors: red, yellow and orange.
• 730 nm: Removal of tattoos for Fitzpatrick Skin Types II-IV to treat the following tattoo colors: green and blue.
• 785 nm: Removal of tattoos for Fitzpatrick Skin Types II-IV to treat the following tattoo colors: green and blue.
• 1064 nm: Removal of tattoos for all Fitzpatrick Skin Types to treat the following tattoo colors: black, brown, green, blue and purple.
The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.
The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V and for treatment of Melasma for Fitzpatrick Skin Types I-IV.
The Resolve handpieces (532 nm HE, 532 nm, and 1064 nm) are also indicated for the treatment of wrinkles in Fitzpatrick Skin Types I-IV.
The Resolve Fusion handpiece (532 nm) is indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.
The PicoWay laser system is indicated for the following at the specified wavelengths:
532 nm:
• Treatment of Melasma for Fitzpatrick Skin Types I-IV.
• Treatment of café au lait macules (CALMs) for Fitzpatrick Skin Types I-IV.
• Treatment of Lentigines for Fitzpatrick Skin Types I-IV.
730 nm:
• Treatment of Lentigines for Fitzpatrick Skin Types I-IV.
1064 nm:
• Treatment of Melasma for Fitzpatrick Skin Types I-IV.
• Treatment of Nevus of Ota for Fitzpatrick Skin Types III-IV.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY K220853

Picoway Laser System

This summary of 510(k) submitted in accordance with the requirements of 21 CFR 807.92.

1. Date Prepared

October 12, 2022

2. Applicant Name

Candela Corporation
251 Locke Drive
Marlborough MA 01752
USA

3. Official Correspondent

Danielle Gibboney
Sr. Regulatory Affairs Specialist
Candela Corporation
251 Locke Drive
Marlborough MA 01752 USA
Phone: 617-904-3820
Email: danielleg@candelamedical.com

4. Product Information

Name of Device: Picoway Laser System

Common/Usual Name: Powered Laser Surgical Instrument

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)

Device Classification: Class II (per 21 CFR Part 878.4810)

Product Code: GEX

5. LEGALLY MARKETED PREDICATE DEVICE FOR CLAIMED EQUIVALENCE:

Predicate Device: Picoway Laser System (K191685)

6. DEVICE DESCRIPTION:

The PicoWay Laser System is a solid-state laser capable of delivering energy at wavelengths of 1064 nm, 532 nm, 785nm, or 730 nm, at extremely short duration in the range of 240-500 (ps). The laser system contains one 755 nm (Alexandrite) laser head which is used to 'pump' (create) the 1064 / 532nm wavelengths. The outputs of the two lasers are optically combined on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 532nm or 1064nm wavelengths. The 532nm or 1064nm output energy is delivered to the skin through an Articulated Arm and Zoom Handpiece (HP) delivery system. There are also 3 hand pieces (Resolve), one for 1064nm and two for 532nm (low energy and high energy), which deliver a 10 x 10 array of focused spots to the skin and 1 Axicon hand piece (Resolve Fusion) for 532nm, which delivers a 10 x 10 array of focused and ring spots to the skin. The following handpieces are cleared to be used with Picoway Laser System

Zoom Handpieces:

- 532 nm
- 1064 nm

Handpieces:

- 730 nm
- 785 nm

Resolve Handpieces:

- 532 nm
- 532 nm HE
- 1064 nm

Resolve Fusion Handpieces:

- 532 nm
- 1064 nm

7. INTENDED USE AND INDICATIONS FOR USE:

The PicoWay laser system is indicated for the following at the specified wavelength:

- 532 nm: Removal of tattoos for Fitzpatrick Skin Types I-III to treat the following tattoo colors: red, yellow and orange.
- 730 nm: Removal of tattoos for Fitzpatrick Skin Types II-IV to treat the following tattoo colors: green and blue.
- 785 nm: Removal of tattoos for Fitzpatrick Skin Types II-IV to treat the following tattoo colors: green and blue.
- 1064 nm: Removal of tattoos for all Fitzpatrick Skin Types to treat the following tattoo colors: black, brown, green, blue and purple.

The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V **and for treatment of Melasma for Fitzpatrick Skin Types I-IV.**

The Resolve handpieces (532 nm HE, 532 nm, and 1064 nm) are also indicated for the treatment of wrinkles in Fitzpatrick Skin Types I-IV.

The Resolve Fusion handpiece (532 nm) is indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

The PicoWay laser system is indicated for the following at the specified wavelengths:

532 nm:

- **Treatment of Melasma for Fitzpatrick Skin Types I-IV.**
- **Treatment of café au lait macules (CALMs) for Fitzpatrick Skin Types I-IV.**
- **Treatment of Lentigines for Fitzpatrick Skin Types I-IV.**

730 nm:

- **Treatment of Lentigines for Fitzpatrick Skin Types I-IV.**

1064 nm:

- **Treatment of Melasma for Fitzpatrick Skin Types I-IV.**
- **Treatment of Nevus of Ota for Fitzpatrick Skin Types III-IV.**

8. TECHNOLOGICAL COMPARISON:

The subject device Picoway Laser System is substantially equivalent and identical in the design, function, and intended use to the Picoway Laser System (K191685). The difference between the subject Picoway Laser System and its predicate is the additional indications for benign pigmented lesions including but not limited to: Nevus of Ota, café au lait macules (CALMs), melasma, and lentigines that this Premarket Notification is proposing. The expanded indications between the subject device and its predicate does not raise any new concerns of safety or effectiveness of the device. Thus, based on the information presented in this Premarket Notification, Picoway Laser System is substantially equivalent to its predicate Picoway Laser System (K191685). Please refer to specification comparison tables in Table 1 and Table 2 for comparisons between intended use/indications for use, and technological & biological characteristic comparison below.

Table 1: Intended/Indication for use comparison table.

Name of Device: **510(k)** **Product Code** **Device Class**	**Picoway Laser System** **Proposed** K220853 GEX Class II	**Picoway Laser System** **Predicate** K191685 GEX Class II
Intended use / Indications:	The PicoWay laser system is indicated for the following at the specified wavelength: • 532 nm: Removal of tattoos for Fitzpatrick Skin Types I-III to treat the following tattoo colors: red, yellow and orange. • 730 nm: Removal of tattoos for Fitzpatrick Skin Types II-IV to treat the following tattoo colors: green and blue. • 785 nm: Removal of tattoos for Fitzpatrick Skin Types II-IV to treat the following tattoo colors: green and blue. • 1064 nm: Removal of tattoos for all Fitzpatrick Skin Types to treat the following tattoo colors: black, brown, green, blue and purple. The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V **and for treatment of Melasma for Fitzpatrick Skin Types I-IV**. The Resolve handpieces (532 nm HE, 532 nm, and 1064 nm) are also indicated for the treatment of wrinkles in Fitzpatrick Skin Types I-IV. The Resolve Fusion handpiece (532 nm) is indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. **The PicoWay laser system with Zoom Handpieces is indicated for the following at the specified wavelengths:**	The PicoWay laser system is indicated for the following at the specified wavelength: 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. 730 nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. 785 nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V. The Resolve handpieces (532 nm HE, 532 nm, 1064 nm) are also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV. The Resolve Fusion handpiece (1064 nm) is indicated for the treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV. The Resolve Fusion handpiece (532 nm) is indicated for the treatment

	532 nm: ○ **Treatment of Melasma for Fitzpatrick Skin Types I-IV.** ○ **Treatment of café au lait macules (CALMs) for Fitzpatrick Skin Types I-IV.** ○ **Treatment of Lentigines for Fitzpatrick Skin Types I-IV.** **730 nm:** ○ **Treatment of Lentigines for Fitzpatrick Skin Types I-IV.** **1064 nm:** ○ **Treatment of Melasma for Fitzpatrick Skin Types I-IV.** ○ **Treatment of Nevus of Ota for Fitzpatrick Skin Types III-IV.**	of benign pigmented lesions in Fitzpatrick Skin Types I-IV.
Similarities/Differences	Identical to Predicate device, but with expanded indications identified in **BOLD.**	Identical to the subject device, but without the expanded indications.

Table 2: Technological & Biological specification comparison

General Specifications	**Picoway Laser System** **Subject Device** Not Assigned				**Picoway Laser System** **Predicate** K191685			
Wavelength	**IDENTICAL** 532 nm	**IDENTICAL** 730 nm	**IDENTICAL** 785 nm	**IDENTICAL** 1064 nm	**IDENTICAL** 532 nm	**IDENTICAL** 730 nm	**IDENTICAL** 785 nm	**IDENTICAL** 1064 nm
Laser Type	**IDENTICAL** Resolve: & Resolve Fusion Double Nd: Yag Zoom: Titanium Sapphire	**IDENTICAL** Handpiece: Titanium Sapphire	**IDENTICAL** Handpiece: Titanium Sapphire	**IDENTICAL** Resolve & Resolve Fusion: Nd: Yag Frequency Zoom: Titanium Sapphire	**IDENTICAL** Resolve: & Resolve Fusion Double Nd: Yag	**IDENTICAL** Zoom: Titanium Sapphire	**IDENTICAL** Zoom: Titanium Sapphire	**IDENTICAL** Resolve & Resolve Fusion: Nd: Yag Frequency Zoom: Titanium Sapphire
Repetition Rate (Hz)	**IDENTICAL** Single 1, 2, 2, 4, 5, 6, 7, 8, 9, 10 Hz				**IDENTICAL** Single 1, 2, 2, 4, 5, 6, 7, 8, 9, 10 Hz			
Fluence Ranges	**IDENTICAL** Zoom Handpiece: 2 mm: 1-00-6.25 J/cm^2 3 mm: 0.040-2.80 J/cm^2 4 mm: 0.30-1.60 J/cm^2 5 mm: 0.20-1.00 J/cm2 6 mm: 0.20-0.72 J/cm2 7 mm: 0.26-0.52 J/cm2 8 mm: 0.20- 0.40 J/cm2				**IDENTICAL** Zoom Handpiece: 2 mm: 1-00-6.25 J/cm^2 3 mm: 0.040-2.80 J/cm^2 4 mm: 0.30-1.60 J/cm^2 5 mm: 0.20-1.00 J/cm2 6 mm: 0.20-0.72 J/cm2 7 mm: 0.26-0.52 J/cm2 8 mm: 0.20- 0.40 J/cm2			

General Specifications	Picoway Laser System Subject Device Not Assigned	Picoway Laser System Predicate K191685
	9 mm: 0.16-0.32 J/cm2 10 mm: 0.13-0.25 J/cm2 Resolve High Energy Handpiece: 0.20-1.50 mJ/µbeam Resolve Low Energy Handpiece: 0.16-0.30 mJ/µbeam Resolve Fusion Handpiece: 0.20-0.70	9 mm: 0.16-0.32 J/cm2 10 mm: 0.13-0.25 J/cm2 Resolve High Energy Handpiece: 0.20-1.50 mJ/µbeam Resolve Low Energy Handpiece: 0.16-0.30 mJ/µbeam Resolve Fusion Handpiece: 0.20-0.70
Pulse Duration	**IDENTICAL** 240-500 picosecond	**IDENTICAL** 240-500 picosecond
Spot Size (mm)	**IDENTICAL** Zoom: 2 to 10 in increments of 1mm Resolve: 6 mm x 6 mm array in 10 x 10 matrix Resolve Fusion: 6 mm x 6 mm array in 10 x 10 matrix	**IDENTICAL** Zoom: 2 to 10 in increments of 1mm Resolve: 6 mm x 6 mm array in 10 x 10 matrix Resolve Fusion: 6 mm x 6 mm array in 10 x 10 matrix
BIOLOGICAL CHARACTERISTICS		
Patient Contacting Material	**IDENTICAL** Aluminum	**IDENTICAL** Aluminum
SYSTEMS		
Delivery system	**IDENTICAL** Articulated arm with dedicate handpiece	**IDENTICAL** Articulated arm with dedicate handpiece
User Interface	**IDENTICAL** Touchscreen with GUI	**IDENTICAL** Touchscreen with GUI
Electrical Power	**IDENTICAL**	**IDENTICAL**

General Specifications	Picoway Laser System Subject Device Not Assigned	Picoway Laser System Predicate K191685
	200-240 VAC, 50/60 HZ, 4600 VA single	200-240 VAC, 50/60 HZ, 4600 VA single
Physical Dimensions /Weight (Console)	**IDENTICAL** 275 lb (125 kg)	**IDENTICAL** 275 lb (125 kg)

9. PERFORMANCE DATA:

Performance Testing: Bench:
The performance testing of the subject PicoWay Laser System is based on the established testing previous cleared under PicoWay Laster System predicate (K191685). There are no changes in the design therefore the subject Picoway Laser System is based on the established performance testing of the device's predicate.

Performance Testing-Clinical
A systematic literature search, using PubMed, Embase and Cochrane databases, was conducted to identify peer-reviewed articles published during January 1, 2015 to May 31, 2022 in which the PicoWay Laser System was used to treat benign pigmented lesions, with any of the PicoWay Laser Handpieces at 532 nm, 730 nm, 785 nm, and 1064 nm wavelengths. A combination of MeSH terms and free-text searches for the device (picoway laser, picosecond laser) and for pigmented lesions and specific benign pigmented lesions nevus of Ota, CALM (macules) and/or melasma, were included in the search criteria. A supplemental search in ClinicalTrials.gov was performed using similar search terms to identify clinical trials with results relevant to the clinical safety and performance of the Picoway Laser System. The Literature Search methodology and findings are described in detail within the Clinical Literature Summary below.

Nine articles were identified that reported on randomized controlled, or prospective, open label, evaluator-blinded clinical trials or retrospective evaluator-blinded studies that treated at least 10 individuals in each study using the PicoWay Laser System. The studies were conducted in the USA, the UK, Asia (Thailand, China) and the Middle East (Israel) and included a total of 262 subjects (228 females, 34 males; Fitzpatrick Skin Type (FST) I-V) treated for benign pigmented lesions, including nevus of Ota (n=20), café au lait macules (n=32), melasma (n=70) and lentigines (n=140), using the PicoWay Laser System. Melasma was treated with the PicoWay Zoom handpieces (532 nm and/or 1064 nm) and the PicoWay Resolve 1064 nm handpiece alone or combined with 12 weeks of daily application of 4% hydroquinone cream. CALMs were treated with the Zoom 532 nm handpiece; nevus of Ota was treated using the PicoWay Zoom 1064 nm handpiece, and lentigines were treated with the PicoWay 730 nm handpiece and the Zoom 532 nm handpiece. The articles are identified in table 3 below.

Table 3. Identification of Clinical Articles in PicoWay literature search analysis

Article	Title	Indication	PicoWay Laser Handpiece (s)
1	Wong CSM, Chan MWM, Shek SYN, Yeung CK & Chan HHL. Fractional 1064 nm picosecond laser in treatment of melasma and skin rejuvenation in Asians, a	Melasma	Melasma: (Resolve 1064 nm laser)

Article	Title	Indication	PicoWay Laser Handpiece (s)
	prospective study. Lasers Surg Med 2021;53(8):1032-1042.		
2	Kung KY, Shek SYN, Yeung CK, & Chan HHL. Evaluation of the safety and efficacy of the dual wavelength picosecond laser for the treatment of benign pigmented lesions in Asians. Lasers Surg Med 2019;51(1):14-22.	Melasma; CALMs	Melasma: (Zoom 1064 nm laser) CALM: (Zoom 532 nm laser)
3	Chalermchai T, Rummaneethorn P. Effects of a fractional picosecond 1,064 nm laser for the treatment of dermal and mixed type melasma. J Cosmet Laser Ther. 2018 Jun;20(3):134-139. **article included treatement 4% hydroquinone*	Melasma	Melasma: (Resolve 1064 nm laser)
4	Mehrabi JN, Friedman O, Al-Niaimi F & Artzi, O. Retrospective photographic review of nontattoo indications treated by picosecond laser. J Cosmet Dermatol 2020; Mar;19(3):612-621.	Melasma; CALMs; Nevus of Ota	Melasma: (Resolve 1064 nm laser and Zoom 1064 nm or 532 nm lasers) CALM: (Zoom 532 nm laser) Nevus of Ota: (Zoom 1064 nm laser) Lentigines: (Zoom 532 nm laser)
5	Yang H, Guo L, Jia G, Gong X, Wu Q, Zeng R, Zhang M, Ding H, Fang F, Zheng H, Liu X, Ge Y, Yang Y, Lin T. Treatment of nevus of Ota with 1064 nm picosecond Nd:YAG laser: A retrospective study. Dermatol Ther 2021; Nov;34(6):e15152.	Nevus of Ota	Nevus of Ota: (Zoom 1064 nm laser)
6	Artzi O, Mehrabi JN, Koren A, Niv R, Lapidoth M, Levi A. Picosecond 532-nm neodymium-doped yttrium aluminium garnet laser-a novel and promising modality for the treatment of café-au-lait macules. Lasers Med Sci 2018 May;33(4):693-697.	CALMs	CALM: (Zoom 532 nm laser)
7	Kauvar ANB, Sun R, Bhawan J, Singh G, Ugonabo N, Feng H, Schomacker K. Treatment of facial and non-facial lentigines with a 730 nm picosecond titanium: Sapphire laser is safe and effective. Lasers Surg Med. 2022 Jan;54(1):89-97.	Lentigines	Lentigines (730 nm laser)

Article	Title	Indication	PicoWay Laser Handpiece (s)
8	Vachiramon V, Namasondhi A, Anuntrangsee T, Jurairattanaporn N. Randomized, evaluator-blinded comparative study of a potassium titanyl phosphate (KTP) 532-nm picosecond laser and an alexandrite 755-nm picosecond laser for the treatment of solar lentigines in Asians. J Cosmet Dermatol. 2022 Feb 7.	Lentigines	Lentigines (Zoom 532 nm laser)
9	Vachiramon V, Iamsumang W, Triyangkulsri K. Q-switched double frequency Nd:YAG 532-nm nanosecond laser vs. double frequency Nd:YAG 532-nm picosecond laser for the treatment of solar lentigines in Asians. Lasers Med Sci. 2018 Dec;33(9):1941-1947.	Lentigines	Lentigines (Zoom 532 nm laser)

Additionally, Candela identified an investigator-initiated prospective, open-label clinical study that had been conducted by Principal Investigator Eric F. Bernstein, M.D. of Main Line Center Surgery for Laser Surgery in Ardmore, PA. In this study, treatment of melasma with the PicoWay® device using the 1064nm Resolve handpiece resulted in statistically significant improvement ($p<0.05$) in mean mMASI scores at 3-month and 8-month follow-up visits in comparison to baseline. Majority of the subjects (≥70 %) demonstrated improvement in the appearance of melasma at both follow-up visits. Investigator and Subject satisfaction ratings with treatment outcome were remarkably high (> 85%). Treatments were well tolerated, and there were no device-related adverse events.

10. SUBSTANTIAL EQUIVALENCE COMPARISON

When comparing the subject Picoway Laser System to the predicate device Picoway Laser System (K191685) the additional indications for use does not raise any new issues of safety and effectiveness. There are no technological changes between the subject and predicate device. The Picoway Laser System is substantially equivalent, in terms of technological characteristics, performance, and intended use to the predicate device Picoway Laser System (K191685) as they are identical.