April 30, 2025

Medency S.r.l.
Alessandro Zorgati
Regulatory Affairs Specialist
Via degli Ontani, 48
Vicenza, IT 36100
Italy

Re: K232222
Trade/Device Name: Primo Dental Laser (Primo, Primo Komfort, Primo Lite, Primo Blue, and Primo Triplo)
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: NVK, GEX

Dear Alessandro Zorgati:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 27, 2023. Specifically, FDA is updating this SE Letter to correct an error in the device trade name included in the IFU and 510(k) Summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Adjodha, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, 301-796-6276, Michael.Adjodha@fda.hhs.gov.

Sincerely,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

November 27, 2023

Medency S.r.l.
Alessandro Zorgati
Regulatory Affairs Specialist
Via degli Ontani, 48
Vicenza, IT 36100
ITALY

Re: K232222
Trade/Device Name: Primo Dental Laser
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: NVK, GEX
Dated: November 14, 2023
Received: November 14, 2023

Dear Alessandro Zorgati:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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.

Submission Number *(if known)*

K232222

Device Name

Primo Dental Laser (Primo, Primo Komfort, Primo Lite, Primo Blue, and Primo Triplo)

Indications for Use *(Describe)*

1. Dental Soft Tissue Indications
incision, excision, vaporization and coagulation of oral soft-tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunction to root canal therapy
- Reduction of gingival hypertrophy
- Soft-tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty
- Tissue retraction for impression
- Reduction of bacterial level (decontamination) and inflammation

2. Laser Periodontal Procedures
- Laser soft-tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft-tissue within periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft-tissue within periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility).

3. Whitening
- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

4. Pain Therapy
- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor pain, or muscle spasm, minor sprains and strains, and

minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. CONTACT DETAILS

Applicant Name	Medency Srl
Applicant Address	Via degli Ontani, 48 Vicenza IT 36100 Italy
Applicant Contact Telephone	+(39) 0444371462
Applicant Contact	Alessandro Zorgati
Applicant Contact Email	quality@medency.com

2. DEVICE NAME

Device Trade Name	Primo Dental Laser (Primo, Primo Komfort, Primo Lite, Primo Blue, and Primo Triplo)
Common Name	Laser surgery instrument for use in general and plastic surgery and dermatology
Classification Name	Powered Laser Surgery Instrument
Regulation Number	878.4810
Product Code	GEX

3. LEGALLY MARKED PREDICATE DEVICE

PREDICATE	PREDICATE TRADE NAME	PRODUCT CODE
PRIMARY		
K192430	EPIC 980 (Biolase Inc)	GEX
SECONDARY		
K100474	QuickLase 980, 810 and Dual+ (QuickLase Limited)	GEX
K180044	SIROLaser Blue (Dentsplay Sirona)	GEX
K172771	Epic Pro 940 (Biolase Inc)	GEX
K152032	ELUMI 810 + 980 Soft Tissue Laser (Azena Medical, LLC)	GEX

4. DEVICE DESCRIPTION SUMMARY

Primo Dental Laser is a laser medical device with surgical and therapeutic effects mainly used in dental and oral care. It's a portable medical device composed by a console, the principal component of the device, connected to a handpiece through an optical fiber, which represent the applied parts.

Primo Dental Laser is a medical device used for a great variety of dental treatment including Surgery, Decontamination, Biostimulation and Therapy. All this due to the selection of protocols favourable through a wide spectrum of specialties.

Laser radiation is produced by a laser diode. This component, a semiconductor, is able to produce a laser radiation with a wavelength characteristic of the semiconductor itself.
Primo Dental Laser has the following characteristics: is transportable and equipped with an internal battery to be independent from the power supply. Laser emission occurs with a wireless pedal control, also powered by batteries.
The laser radiation is emitted through a delivery system connected to a handpiece that allows the light to be brought to the patient.

5. INTENDED USE/INDICATIONS FOR USE

1. Dental Soft Tissue Indications
incision, excision, vaporization and coagulation of oral soft-tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunction to root canal therapy
- Reduction of gingival hypertrophy
- Soft-tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty
- Tissue retraction for impression
- Reduction of bacterial level (decontamination) and inflammation

2. Laser Periodontal Procedures
   - Laser soft-tissue curettage
   - Laser remuval of diseased, infected, inflamed and necrosed soft-tissue within periodontal pocket
   - Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft-tissue within periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility).

3. Whitening
   - Light activation for bleaching materials for teeth whitening
   - Laser-assisted whitening/bleaching of teeth

4. Pain Therapy
   - Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

6. INDICATION FOR USE COMPARISON

The subject device, Primo Dental Laser family of medical devices, is indicated for dental soft tissue indications, incision, excision, vaporization, ablation and coagulation oforal soft-tissues. The intended use of the main predicate device Epic 980 (K192430) is incision, excision, vaporization, ablation and coagulation of oral soft tissue. Looking at specific treatments there is only one difference in the treatment of 'Decontamination' that is not performed by the predicate. Respect to other predicates, indications for use are almost identical except for minor differences like: predicates QuickLase (K100474) does not perform whitening/bleaching for teeth compared to Primo Dental Laser; then, SirolLase Blue (K180044) and Epic Pro 940 (K172771) do not perform decontamination compared to Primo Dental Laser. These missing treatments are anyway covered by the other predicates.
These are slight differences that do not influence negatively the equivalence between Primo Dental Laser intended use and the one of predicates. Therefore, intended use of Primo Dental Laser does not constitute a new intended use.

7. TECHNOLOGICAL COMPARISON

Talking about <u>wavelengths</u>:

- the different models of Primo Dental Laser family of devices operate at the following wavelengths: 450nm, 810nm, 940nm and 980nm used individually or in combination with each other (**they are always used one at a time and never simultaneously**).
- Predicate devices K192430, K100474, K180044 and K152032 claim equivalence to the models that operate at 980nm wavelength.
- Predicate devices K100474 and K152032 claim equivalence to the models that operate at 810nm wavelength.
- Predicate device K180044 claims equivalence to the models that operate at 450nm wavelength.
- Predicate device K180044 claims equivalence to the model that operate at 635nm wavelength, since the difference is negligible.

Therefore, the predicate devices are substantially equivalent to the proposed family of medical devices.

Talking about the power:

- Since all predicate devices reach a maximum power equal or higher than 10W (the maximum power of Primo Dental Laser is covered), are substantially equivalent to the proposed family of medical devices.
- Primo Dental Laser family is under the GEX category, a laser surgical instrument. The different models of Primo Dental Laser family of devices operate at the following wavelengths: 450nm, 635nm, 810nm, 940nm and 980nm used individually or in combination with each other (they are always used one at a time and never simultaneously).
- The radiation emitted by the diode laser is delivered to the tissue through the optical fiber or through the use of an accessory.

Primo Dental Laser shares the same technological characteristic as the predicate devices including:

- the same laser source: solid state diode producing invisible infrared energy;
- the same wavelengths: 450nm, 635nm, 810nm, 940nm and 980nm taken individually from predicate devices;
- the same intended use: incision, excision, vaporization, ablation and coagulation of oral soft tissue;
- the same indications for use;
- the same patient-contacting components: glass fiber used in contact and non-contact mode;
- the same use environment;
- the same tissue type and application regimen;
- the same principle of operation and emission mode: continuous wave, pulsed or both the same control mechanism;
- similar design consisting of software-operated portable laser unit, initiated by a footswitch similar delivery system comprising of an optical fiber, handpiece and single use disposable tips / accessories;
- the same human factors of user interface.

Although some parameters such as maximum power output, power density, pulse rate differ among the devices, these differences do not result is a significantly different clinical performance since the settings and used for the expanded indications as well as the treatment regimen are essentially the same. Therefore, the consolidation of clinical applications creates no new risks or safety concerns.

In conclusion, Primo Dental Laser family has the same intended use and the same or substantially equivalent technical specifications and mechanism of action as compared with the named predicated devices.

The proposed laser device is substantially equivalent to the mentioned predicate devices. Performance testing to validate the safety and effectiveness of Primo Dental Laser include electrical safety, electromagnetic compatibility, and validation testing of both hardware and software functions.

Specifications	Proposed device	Primary Predicate device	Secondary Predicate devices			
Trade name	Medency Primo Dental Laser	Biolase Inc. Epic 980	QuickLase Limited QuickLase 980, 810 and Dual+	Dentsply Sirona SIROLaser Blue	Biolase Inc. Epic Pro 940	Azena Medical, LLC ELUMI 810 + 980 Soft Tissue Laser
FDA K/number	K232222	K192430	K100474	K180044	K172771	K152032
Class	II	II	II	II	II	II
Laser medium	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser
Laser class	IV	IV	IV	IV	IV	IV
Wavelength	450±10nm 810±10nm 940±10nm 980±10nm (635+810+980) nm (450+635+810) nm (450+635+980) nm	980±10nm	980±10nm 810±10nm (810+980) nm	970±10nm 660±10nm 445±10nm	940±10nm	980±10nm 810±10nm (810+980) nm
Target users	Doctors specialized in Dentistry	Doctors specialized in Dentistry	Doctors specialized in Dentistry	Doctors specialized in Dentistry	Doctors specialized in Dentistry	Doctors specialized in Dentistry
Prescription/	Prescription use	Prescription use	Prescription use	Prescription use	Prescription use	Prescription use

over-the-counter use						
Operation modes	Continuous/Pulsed	Continuous/Pulsed	Continuous/Pulsed	Continuous/Pulsed	Continuous/Pulsed	Continuous/Pulsed
Max power	10W	10W	10W	10W	25W	20W
Repetition rate (Frequency)	Up to 25 kHz	Up to 20 kHz	Up to 20 kHz	Up to 10 kHz	Up to 20 kHz	Up to 20 kHz
Aiming beam	650±20 nm	625 - 670 nm	640 – 650 nm	660 nm	650 nm	650 nm
Control panel	Touch screen	Touch screen	Touch screen	Touch screen	Touch screen	Touch screen
Activation	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch
Delivery system	Fiber optic cable, handpiece, accessories.	Fiber optic cable, handpiece, accessories.	Fiber optic cable, handpiece, accessories.	Fiber optic cable, handpiece, accessories.	Fiber optic cable, handpiece, accessories.	Fiber optic cable, handpiece, accessories.
Materials in contact with the patient tissues.	Optical tip	Optical tip	Optical tip	Optical tip	Optical tip	Optical tip
Compliance to standards	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22
Optical tips	Single-use tips varying in length and core Diameter (200 – 400µm)	Quartz single use tips varying in length and core diameter (200 – 400µm)	Single use tips varying in core diameter (200 - 320 µm)	Fiber Diameter: 200 µm, 320 µm	Quartz single-use tips varying in length and core Diameter (200 – 400µm)	Fiber tip diameter: 400 µm core

Sterilization method of optical tips	Steam autoclave	Steam autoclave	Steam autoclave	Optical tips are provided sterile (sterilized by ethylene oxide)	Steam autoclave	Gravity steam sterilization
Curved light guide	Biostimulation handpiece (8 mm diameter)	Not known	Not known	Curved light guides (4 mm, 8mm diameter)	Not known	Not known
Whitening handpiece	40mmx10mm	35mmx8mm	Not known	Not known	Not known	Not known
Therapy handpiece	Bell therapy handpiece (10mm diameter)	30mm diameter	Not known	Not known	Not known	Not known

Indication for use:

Specifications and indications for use of proposed device	**Primary Predicate device**	**Secondary Predicate devices**			
Medency Primo Dental Laser	Biolase Inc. Epic 980	QuickLase Limited QuickLase 980, 810 and Dual+	Dentsply Sirona SIROLaser Blue	Biolase Inc. Epic Pro 940	Azena Medical, LLC ELUMI 810 + 980 Soft Tissue Laser
K232222	K192430	K100474	K180044	K172771	K152032
Dental soft tissue indications: incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and interdental gingival and epithelial lining of free gingiva.	✓	✓	✓	✓	✓
Excisional and incisional biopsies	✓	✓	✓	✓	✓

Exposure of unerupted teeth	✓	✓	✓	✓	✓
Fibroma removal	✓	✓	✓	✗	✓
Frenectomy	✓	✓	✓	✓	✓
Gingival troughing for crown impressions	✓	✓	✓	✓	✓
Gingivectomy	✓	✓	✓	✓	✓
Gingivoplasty	✓	✓	✓	✓	✓
Gingival incision and excision	✓	✓	✓	✓	✓
Hemostasis and coagulation	✓	✓	✓	✓	✓
Implant recovery	✓	✓	✓	✓	✓
Incision and drainage of abscess	✓	✓	✓	✓	✓
Leukoplakia	✓	✓	✓	✓	✓
Operculectomy	✓	✓	✓	✓	✓
Oral papillectomies	✓	✓	✓	✓	✓
Pulpotomy	✓	✓	✓	✓	✓
Pulpotomy as an adjunct to root canal therapy	✓	✓	✓	✓	✓
Reduction of gingival hypertrophy	✓	✓	✓	✓	✓
Soft-tissue crown lengthening	✓	✓	✓	✓	✓
Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa	✓	✓	✓	✓	✓
Vestibuloplasty	✓	✓	✓	✓	✓
Tissue retraction for impression	✓	✓	✓	✓	✓

Laser soft-tissue curettage	✓	✓	✓	✓	✓
Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket	✓	✓	✓	✓	✓
Sulcular debridement	✓	✓	✓	✓	✓
Light activation for bleaching materials for teeth whitening	✓	✗	✓	✓	✓
Laser-assisted whitening/bleaching of teeth	✓	✗	✓	✓	✓
Reduction of bacterial Level (decontamination) and inflammation	✗	✓	✗	✗	✓

8. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

- Biocompatibility Testing
  The biocompatibility evaluation of the submitted device was conducted in accordance with "ISO 10993-1 Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process". Cytotoxicity, Sensitization, Pyrogenicity, and Irritation biological tests were performed on the applied part optical tips: the results demonstrate biocompatibility.

- Electrical Safety and Electromagnetic Compatibility (EMC)
  Electrical safety and electromagnetic compatibility testing conducted according to the current revisions of recognized standards demonstrate compliance with the standards:
  - IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for safety – electromagnetic compatibility (EMC)- requirements and tests.
  - IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
  - IEC 60601-2-22: 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: Safety of Laser Products – Part 1: Equipment classification and requirements.

- Software Verification and Validation
  Software contained in the Epic 980 was developed in accordance with IEC 62304. Software verification and validation testing were performed, and documentation provided in accordance with the FDA guidance document “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices”.

- Clinical Testing
  Clinical testing was not performed since there was no change to the intended use and indications for use and the performance characteristics between the subject device and its predicates.

- Conclusions
  Comparison of the Primo Dental Laser subject device with Epic 980 primary predicate (K192430), and secondary predicates devices QuickLase 980, 810 and Dual+ (K100474), SIROLaser Blue (K180044), Epic Pro 940 (K172771) and ELUMI 810 + 980 Soft Tissue Laser (K152032) supports substantial equivalence of the Primo Dental Laser to the identified legally-marketed devices.