



July 11, 2018

Syneron-Candela Corp
Sharon Timberlake
VP. Global Regulatory and Clinical Affairs
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K181523

Trade/Device Name: CO₂RE 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: June 8, 2018

Received: June 11, 2018

Dear Sharon Timberlake:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181523

Device Name

CO₂RE Laser System

Indications for Use (Describe)

The CO₂RE is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee).

The CO₂RE is indicated for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

The Standard Handpiece of the CO₂RE System is indicated for the following:

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- laser skin resurfacing
- laser dermabrasion
- laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) for the treatment of:

- wrinkles, rhytids, and furrows (including fine lines and texture irregularities)

Clinical literature demonstrates that skin resurfacing of wrinkles, rhytids, and furrows with CO₂ laser increases the amount of sub-epidermal collagen.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart, and verruca seborrheica;
- vermilionectomy of the lip;
- cutaneous horns;
- solar/actinic elastosis;
- cheilitis, including actinic cheilitis;
- lentigines, including lentigo maligna or Hutchinson's malignant freckle
- uneven pigmentation/ dyschromia;
- acne scars;
- surgical scars;
- keloids including acne keloidalis nuchae;
- hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum);
- tattoos;
- telangiectasia;
- removal of small skin tumors, including periungual (Koenen) and subungual fibromas;
- superficial pigmented lesions;
- adenosebaceous hypertrophy or sebaceous hyperplasia;
- rhinophyma reduction;
- cutaneous papilloma (skin tags);
- milia;
- debridement of eczematous or infected skin;

-
- basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;
 - nevi, including spider, epidermal and protruding;
 - neurofibromas;
 - laser de-epithelialization;
 - tricoepitheliomas;
 - xanthelasma palpebrarum;
 - syringoma

Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy. Vaporization/coagulation of:

- benign/malignant vascular/avascular skin lesions;
- Verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts.

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of:

- verrucae vulgares/plantar (warts), including paronychial, periungal, and subungual warts;
- fungal nail treatment;
- porokeratoma ablation;
- ingrown nail treatment;
- neuromas/fibromas, including Morton's neuroma;
- debridement of ulcers;
- other soft tissue lesions.

Laser ablation, vaporization and /or excision in podiatry for complete or partial matrixectomy.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of:

- leukoplakia, including oral, larynx, uvula, palatal, upper latera pharyngeal tissue;
- nasal obstruction;
- adult and juvenile papillomatosis polyps;
- polypectomy of nose and nasal passages; lymphangioma removal;
- removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;
- superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease;
- rhinophyma;
- verrucae vulgares (warts);

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions;
- leukoplakia (vulvar dystrophies);
- herpes vaporization;
- urethral caruncle vaporization;
- cervical dysplasia;
- benign and malignant tumors;

Dental/Oral Surgery

Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- treatment of ulcerous lesions, including aphthous ulcers;
- excision and ablation of benign and malignant lesions;
- leukoplakia;

Genitourinary

Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include:

-
- benign and malignant lesions of external genitalia;
 - condyloma;
 - erythroplasia

The Fractional Handpiece of the CO₂RE System is indicated for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

The Surgical Handpiece of the CO₂RE System is indicated for the following:

Dermatology & Plastic Surgery

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- vermillionectomy of the lip;
- cutaneous horns;
- removal of small skin tumors, including periungual (Koenen) and subungual fibromas;
- rhinophyma reduction;
- basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;
- neurofibromas;

Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy. Vaporization/coagulation of:

- benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- Lipectomy;
- Verrucae and seborrhoecae vulgares, including paronychial, periungual, and subungual warts.

Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation.

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of:

- verrucae vulgares/plantar (warts), including paronychial, periungual, and subungual warts;

Laser ablation, vaporization and /or excision in podiatry for complete or partial matrixectomy.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of:

- choanal atresia,
- nasal obstruction;
- adult and juvenile papillomatosis polyps; polypectomy of nose and nasal passages; lymphangioma removal;
- removal of vocal cord/fold nodules, polyps and cysts;
- removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;
- laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue;
- Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodiverticulostomy (ELAED)];
- stenosis, including subglottic stenosis;
- tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil ablation/tonsillotomy;
- pulmonary bronchial and tracheal lesion removal;
- benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial);
- benign and malignant lesions and fibromas (nose and nasal passages);
- benign and malignant tumors and fibromas (oral);
- stapedotomy/stapedectomy; acoustic neuroma in the ear;
- superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease;
- telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
- cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea;
- myringotomy/tympanostomy (tympanic membrane fenestration);
- uvulopalatoplasty (LAUP, laser UPPP);

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- turbinectomy and turbinate reduction/ablation; septal spur ablation/reduction and septoplasty; partial glossectomy;
 - tumor resection on oral, subfacial and neck tissues;
 - rhinophyma;
 - verrucae vulgares (warts);
 - gingivoplasty/gingivectomy.

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions;
- incision and drainage (I&D) of Bartholin's and nabothian cysts;
- benign and malignant tumors;
- hemangiomas.

GYN Laparoscopy

Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of:

- endometrial lesions, including ablation of endometriosis;
- excision/lysis of adhesions;
- salpingostomy
- oophorectomy/ovariectomy; fimbrioplasty;
- metroplasty;
- microsurgery (tubal);
- uterine myomas and fibroids;
- ovarian fibromas and follicle cysts;
- uterosacral ligament ablation;
- hysterectomy.

Neurosurgery

Laser incision, excision, ablation and/or vaporization and of soft tissue in neurosurgery for the treatment of:

Cranial

- posterior fossa tumors;
- peripheral neurectomy;
- benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas and large tumors);
- arteriovenous malformation;
- pituitary gland tumors (transphenoidal approach).

Spinal Cord

- incision/excision and vaporization of benign and malignant tumors and cysts;
- intra- and extradural lesions;
- laminectomy/ laminotomy/ microdiscectomy.

Orthopedics

Incision/excision and vaporization and of soft tissue in orthopedic surgery. Applications include:

Arthroscopy

- meniscectomy;
- chondromalacia;
- chondroplasty;
- ligament release (lateral and other);
- excision of plica;
- partial synovectomy.

General

- debridement of traumatic wounds;
- debridement of decubitus and diabetic ulcers;
- microsurgery;
- artificial joint revision;
- PMMA removal.

General/Thoracic Surgery

Incision, excision and vaporization and of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include:

- debridement of decubitus ulcers, stasis, diabetic and other ulcers;
- mastectomy;
- debridement of bums;
- rectal and anal hemorrhoidectomy;
- breast biopsy;
- reduction mammoplasty;
- cytoreduction for metastatic disease;
- laparotomy and laparoscopic applications;
- mediastinal and thoracic lesions and abnormalities;
- skin tag vaporization;
- atheroma;
- cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips;
- pilonidal cyst removal and repair;
- abscesses;
- other soft tissue applications.

Dental/Oral Surgery

Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- gingivectomy- removal of hyperplasias;
- gingivoplasty;
- incisional and excisional biopsy;
- incision of infection when used with antibiotic therapy;
- frenectomy (frenum release);
- excision and ablation of benign and malignant lesions;
- homeostasis;
- operculectomy;
- crown lengthening;
- removal of soft tissue, cysts and tumors;
- oral cavity tumors and hemangiomas;
- abscesses;
- extraction site hemostasis;
- salivary gland pathologies;
- preprosthetic gum preparation;
- partial glossectomy;
- periodontal gum resection.

Genitourinary

Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include:

- benign and malignant lesions of external genitalia;
- condyloma;
- Phimosi;
- Erythroplasia.

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
CO₂RE System**

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

1. DATE PREPARED

June 8, 2018

2. APPLICANT NAME

Candela Corporation
530 Boston Post Road
Wayland, MA 01778
P: (508) 358-0304

M: (617) 957-1434

3. OFFICIAL CORRESPONDENT

Sharon Timberlake, MSHS, RAC, CCRA
VP, Global Clinical & Regulatory Affairs
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Wayland, MA 01778
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4. DEVICE INFORMATION

Proprietary Name:	CO ₂ RE Laser System
Common/Usual Name:	CO ₂ Laser
Classification Name:	Laser surgical instrument for use in General and Plastic surgery and in dermatology (21 CFR Section 878.4810)
Product Code:	GEX
Device Classification:	Class 2
Laser Classification:	Class IV

5. PREDICATE DEVICE

Syneron CO₂RE Laser System (K151655)

6. INDICATIONS FOR USE

The CO2RE is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee).

The CO2RE is indicated for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

The Standard Handpiece of the CO2RE System is indicated for the following:

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- laser skin resurfacing
- laser dermabrasion
- laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) for the treatment of:

- wrinkles, rhytids, and furrows (including fine lines and texture irregularities)

Clinical literature demonstrates that skin resurfacing of wrinkles, rhytids, and furrows with CO2 laser increases the amount of sub-epidermal collagen.

- Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:
- keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart, and verruca seborrheica;
- vermillionectomy of the lip;
- cutaneous horns;
- solar/actinic elastosis;
- cheilitis, including actinic cheilitis;
- lentigines, including lentigo maligna or Hutchinson's malignant freckle
- uneven pigmentation/ dyschromia;
- acne scars;
- surgical scars;
- keloids including acne keloidalis nuchae;
- hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum);
- tattoos;
- telangiectasia;
- removal of small skin tumors, including periungual (Koenen) and subungual fibromas;
- superficial pigmented lesions;
- adenosebaceous hypertrophy or sebaceous hyperplasia;

- rhinophyma reduction;
- cutaneous papilloma (skin tags);
- milia;
- debridement of eczematous or infected skin;
- basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;
- nevi, including spider, epidermal and protruding;
- neurofibromas;
- laser de-epithelialization;
- tricoepitheliomas;
- xanthelasma palpebrarum;
- syringoma

Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy.

Vaporization/coagulation of:

- benign/malignant vascular/avascular skin lesions;
- Verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts.

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of:

- verrucae vulgares/plantar (warts), including paronychial, periungal, and subungual warts;
- fungal nail treatment;
- porokeratoma ablation;
- ingrown nail treatment;
- neuromas/fibromas, including Morton's neuroma;
- debridement of ulcers;
- other soft tissue lesions.

Laser ablation, vaporization and /or excision in podiatry for complete or partial matrixectomy.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of:

- leukoplakia, including oral, larynx, uvula, palatal, upper latera pharyngeal tissue;
- nasal obstruction;
- adult and juvenile papillomatosis polyps;
- polypectomy of nose and nasal passages;
- lymphangioma removal;

- removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;
- superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease;
- rhinophyma;
- verrucae vulgares (warts);

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions;
- leukoplakia (vulvar dystrophies);
- herpes vaporization;
- urethral caruncle vaporization;
- cervical dysplasia;
- benign and malignant tumors;

Dental/Oral Surgery

Incision/excision and vaporization of soft tissue in dentistry and oral surgery.

Applications include:

- treatment of ulcerous lesions, including aphthous ulcers;
- excision and ablation of benign and malignant lesions;
- leukoplakia;

Genitourinary

Incision/excision and vaporization and of soft tissue in genitourinary procedures.

Applications include:

- benign and malignant lesions of external genitalia;
- condyloma;
- erythroplasia

The Fractional Handpiece of the CO₂RE System is indicated for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

The Surgical Handpiece of the CO₂RE System is indicated for the following:

Dermatology & Plastic Surgery

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- vermillionectomy of the lip;
- cutaneous horns;
- removal of small skin tumors, including periungual (Koenen) and subungual fibromas;
- rhinophyma reduction;
- basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;
- neurofibromas;

Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy.

Vaporization/coagulation of:

- benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- Lipectomy;
- Verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts.

Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation.

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of:

- verrucae vulgares/plantar (warts), including paronychial, periungal, and subungual warts;
- Laser ablation, vaporization and /or excision in podiatry for complete or partial matrixectomy.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of:

- choanal atresia,
- nasal obstruction;
- adult and juvenile papillomatosis polyps;
- polypectomy of nose and nasal passages;
- lymphangioma removal;
- removal of vocal cord/fold nodules, polyps and cysts;
- removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;
- laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue;

- Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodiverticulostomy (ELAED)];
- stenosis, including subglottic stenosis;
- tonsillectomy (including tonsillar cryptolysis, neoplasia) and tonsil ablation/tonsillotomy;
- pulmonary bronchial and tracheal lesion removal;
- benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial);
- benign and malignant lesions and fibromas (nose and nasal passages);
- benign and malignant tumors and fibromas (oral);
- stapedotomy/stapedectomy; acoustic neuroma in the ear;
- superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease;
- telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
- cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea;
- myringotomy/tympanostomy (tympanic membrane fenestration);
- uvulopalatoplasty (LAUP, laser UPPP);
- turbinectomy and turbinate reduction/ablation; septal spur ablation/reduction and septoplasty; partial glossectomy;
- tumor resection on oral, subfacial and neck tissues;
- rhinophyma;
- verrucae vulgares (warts);
- gingivoplasty/gingivectomy.

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions;
- incision and drainage (I&D) of Bartholin's and nabothian cysts;
- benign and malignant tumors;
- hemangiomas.

GYN Laparoscopy

Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of:

- endometrial lesions, including ablation of endometriosis;
- excision/lysis of adhesions;

- salpingostomy
- oophorectomy/ovariectomy; fimbrioplasty;
- metroplasty;
- microsurgery (tubal);
- uterine myomas and fibroids;
- ovarian fibromas and follicle cysts;
- uterosacral ligament ablation;
- hysterectomy.

Neurosurgery

Laser incision, excision, ablation and/or vaporization and of soft tissue in neurosurgery for the treatment of:

Cranial

- posterior fossa tumors;
- peripheral neurectomy;
- benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas and large tumors);
- arteriovenous malformation;
- pituitary gland tumors (transphenoidal approach).

Spinal Cord

- incision/excision and vaporization of benign and malignant tumors and cysts;
- intra- and extradural lesions;
- laminectomy/ laminotomy/ microdiscectomy.

Orthopedics

Incision/excision and vaporization and of soft tissue in orthopedic surgery. Applications include:

Arthroscopy

- menisectomy;
- chondromalacia;
- chondroplasty;
- ligament release (lateral and other);
- excision of plica;
- partial synovectomy.

General

- debridement of traumatic wounds;
- debridement of decubitus and diabetic ulcers;
- microsurgery;
- artificial joint revision;
- PMMA removal.

General/Thoracic Surgery

Incision, excision and vaporization and of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include: debridement of decubitus ulcers, stasis, diabetic and other ulcers; mastectomy;

- debridement of bums;
- rectal and anal hemorrhoidectomy;
- breast biopsy;
- reduction mammoplasty;
- cytoreduction for metastatic disease;
- laparotomy and laparoscopic applications;
- mediastinal and thoracic lesions and abnormalities;
- skin tag vaporization;
- atheroma;
- cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips;
- pilonidal cyst removal and repair;
- abscesses;
- other soft tissue applications.

Dental/Oral Surgery

- Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:
- gingivectomy- removal of hyperplasias;
- gingivoplasty;
- incisional and excisional biopsy;
- incision of infection when used with antibiotic therapy;
- frenectomy (frenum release);
- excision and ablation of benign and malignant lesions;
- homeostasis;
- operculectomy;
- crown lengthening;
- removal of soft tissue, cysts and tumors;
- oral cavity tumors and hemangiomas;
- abscesses;
- extraction site hemostasis;
- salivary gland pathologies;
- preprosthetic gum preparation;
- partial glossectomy;
- periodontal gum resection.

Genitourinary

Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include:

- benign and malignant lesions of external genitalia;
- condyloma;
- Phimosis;
- Erythroplasia.

7. DEVICE DESCRIPTION

The CO₂RE System is a computer controlled radio-frequency (RF) excited carbon dioxide (CO₂) laser system that delivers CO₂ energy to the target treatment area at 10,600 nm. The CO₂RE Laser System is comprised of multiple components, including the control unit and six handpieces. Laser is transmitted to the tissue via a series of lenses integrated into the articulated arm. The CO₂ laser energy is absorbed by water in tissue to achieve its intended treatment effects.

8. TECHNOLOGICAL CHARACTERISTICS

The CO₂RE System technological characteristics are very similar to those of the predicate devices. The CO₂RE System and its predicate devices are all RF excited CO₂ laser systems that operate at the same or similar parameters, including wavelength, pulse duration, maximum laser power, and maximum energy. The systems are comprised of the same or similar components for the same intended use.

9. PERFORMANCE DATA

The CO₂RE System performs as intended based on the performance data provided in the submission.

Software: Verification and validation testing of the software confirm that the software version is appropriate for release.

Electrical Safety and Electromagnetic Compatibility: The CO₂RE System has been tested for electromagnetic compatibility and electrical safety per the applicable recognized consensus standards (IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-22). Results were passing.

Biocompatibility: Biocompatibility of the patient contacting components of the device has been established per FDA's guidelines.

Sterilization: Sterilization parameters have been validated.

10. SUBSTANTIAL EQUIVALENCE

The CO₂RE System has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The technological differences between the CO₂RE System and its predicate devices do not raise any new

types of safety or effectiveness questions given that the key treatment parameters remain similar between the CO₂RE System and its predicates. Performance testing of the CO₂RE System also demonstrated that the device performs as intended.

11. CONCLUSION

The CO₂RE System is a CO₂ laser surgical instrument for use in general and plastic surgery and in dermatology. Testing demonstrated that the device performs as intended. The CO₂RE System is substantially equivalent to its predicate.