



Bio-Med USA Inc.
Young Chi
CEO
27 New England Drive
Ramsey, New Jersey 07446

November 2, 2018

Re: K182270

Trade/Device Name: Cellene CO2 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: August 22, 2018
Received: August 24, 2018

Dear Young Chi:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <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,

Neil R.P.
Ogden

Digitally signed by Neil R.P.
Ogden
Date: 2018.11.02 10:36:40
-04'00'

For 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)
K182270

Device Name
Cellene CO2 Laser System

Indications for Use (Describe)

The Cellene CO2 laser system 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 Cellene Co2 Laser system is indicated for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

The Standard Handpiece of the Cellene Co2 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 fines 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; chelitis, including actinic chelitis; 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 wart.

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of: Verrucae, vulgares / plantars(warts), including paronychial, periungal, and subungual warts, fungal nail treatment, porokeratoma ablation; ingrown nail treatment; neuromas/fibromas, including morton's neuroma, debridement of ulcers, and 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 lateral 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 Cellene System is indicated for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

The Surgical Handpiece of the Cellene CO2 laser 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 paronychia, 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 paronychia, 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, 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), vulopalatoplasty (LAUP, laser UPPP); turbinectomy and turbinate reduction/ablation, septal spur ablation/reduction and septoplasty, partial glossectomy; tumor resection on oral, subfacial and neck tissues, thimophyma, 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; x 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. 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 burns; 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.

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

As required by CFR 807.92(c)

1. Manufacturer.

Prepared Oct 25, 2018

BISON Medical Co., Ltd.
 Ace High-end tower 6, #1801/1802
 234 Beotkkot-ro, Gasan dong
 GeumCheon -gu, Seoul 153-798, Rep of Korea
 t: 82 2 865 7121, f: 82 2 865 7131

Reg Nr: 3011555967

2. Submitter and Contact person

Bio-Med USA Inc.
 Young Chi, C. E. O.
 27 New England Drive, Ramsey, NJ 07446. U.S.A.
 t: 1-973 278 5222 f: 1 201 934 6030
 e mail: biomedusa@msn.com

Reg 2246683

3. Name of Device

Trade name	:	Cellene Co2 laser
Classification name :	:	Powered, Laser surgical instrument
Common name	:	Co2 Laser System
Regulation	:	878.4810 Class II
Classification Panel	:	General and Plastic Surgery.
Product Code	:	GEX Panel 79
Type of submission	:	Traditional

4. Legally marketed Predicate Device

K103501	Pixel Co2 System	Alma Lasers Inc.
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Cellene Co2 laser system is designed same characteristics such as Construction, Energy rate, Pulse Duration, applied same 3 different Hand pieces, Cooling system and Intended use as already cleared predicate device K103501 by Alma Laser Inc.

5. Device Description

The Cellene Co2 Laser system is a computer controlled Radio Frequency system that delivery Co2 energy to the target treatment area at 10,600nm wave length using three different Handpieces (Standard, Fractional and Surgical), This Co2 laser energy is absorbed by water in tissue to achieve its intended treatment effects.

and system consist of,

laser tube : placed in the mixed crystals of copper pipe to the heater and produces a laser beam,

Resonator : amplifies the beam, through the Xe-gas contained lamp

lamp : Xe-gas contains high pressure lamp to increase specific laser beam

This converted light energy creates the CO₂ laser and exhaust from the crystal and amplified into a specific wave length. Laser energy produced is delivered to the Tissue by means of an articulated arm and a specially designed Hand Piece.

The Physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam, and is able to activate laser emission using Foot Switch. Laser parameters and other system features are controlled from a display panel located on the front of the power supply unit.

This system also consist of

Optic main Bench assembly, Articulated Arm, 3 Hand pieces,
LCD control panel, Cooling system, Foot Pedal Switch,

6. Performance test

Clinical test data is not provided in this submission. But, manufactured in accordance with both mandatory and voluntary standard of

IEC60601-1 part 1 : General requirement for basic safety and essential performance
IEC60601-1-2: 2007 Electro Magnetic Compatibility test
IEC60601-2-2 : performance of high frequency surgical equipment and accessories
IEC60601-2-22: Performance of Surgical, Cosmetic, Therapeutic and Diagnostic laser
IEC60601-1 Part 1-6 : General requirement for safety-Collateral Standard: usability
IEC60825-1, 2nd Ed Part 1: Equipment classification and requirements
IEC62304 Medical device software- Software life-cycle processes
Accelerated Aging test of Electrosurgical system electrode hand controlled,
general-purpose, single use

7. Indication for use

The Cellene CO₂ laser system 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 Cellene CO₂ Laser system is indicated for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

**The Standard Handpiece of the Cellene CO₂ 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 paronychia, periungual, and subungual wart.

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of: Verrucae, vulgares / plantars (warts), including paronychia, periungual, and subungual warts, fungal nail treatment, porokeratoma ablation; ingrown nail treatment; neuromas/fibromas, including Morton's neuroma, debridement of ulcers, and 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 lateral pharyngeal tissue; nasal obstruction; x adult and juvenile papillomatosis polyps; x 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 Cellene System is indicated for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

The Surgical Handpiece of the Cellene Co2 laser 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 olynps, polypectomy of nose and nasal passages; lymphangioma removal, removal of vocal cord/fold nodules, polyps and cysts; x 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), vulopalatoplasty (LAUP, laser UPPP); turbinectomy and turbinate reduction/ablation, septal spur ablation/reduction and septoplasty, x partial glossectomy; x tumor resection on oral, subfacial and neck tissues, thimophyma, 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 acuminate, 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 nubuthian 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; x 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

Xmenisectomy, chondromalacia, chondrolasty, ligament release (lateral and other) excision of plica, partial synovectomy. 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.

8. Biocompatibility

Following is the list of parts having direct contact with the patients. and performed Biocompatibility tests in compliance with ISO10993.

Part Hand Piece Probe	Contact materials PC (Polycarbonate)	Nature of body contact direct	Duration Limited <_24 hrs
Test Item	Test and control	Result	Others
Cytotoxicity Study	L-929Cells	Pass	ISO10993-5
Maximization / Sensitization	Polar	Pass	ISO10993-10
Intracutaneous Reactivity Study	Polar	Pass	ISO10993-10

9.Sterilization.

The Cellene Co2 Laser system is non sterilized

10. Conclusion.

The Cellene Co2 Laser system, in this submission, is substantially equivalent to several already cleared predicate device in respect to the Intended use, Main function, Technology, Principal operation and performance. And every safety test report show it as safe and effective as predicate device and it does not raise any additional issues for safety and effectiveness.