

510(k) SUMMARY

Title: Quanta System's Diode Medical Laser Family

Submitter: Quanta System SpA  
via IV Novembre,116  
21058 Solbiate  
Olona VA / Italy

Contact: Dr. Isabella Carrer  
Medical Division Manager

Date Prepared: May 8, 2007

Device Trade Name: Quanta System Diode Medical Laser Family

Common Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification Name: Instrument, surgical, powered, laser  
GEX  
21 C.F.R. 878.4810

Predicate Devices:

- PhotoMedex, Inc.'s LaserPro Surgical Diode Laser System (K042211)
- Diomed, Inc. EVLT Kit and DPlus Lasers (K041957)
- BioLase Technology, Inc EZLase Dental Diode Laser system (K061898)
- INTERmedic Arfran, S.A. INTERmedic Diode Laser Family (K053540)
- Dornier MedTech America, Inc Dornier Diode Laser Family (K020339)

Intended Use /  
Indications for Use: 808 nm, 940 nm, 980nm Wavelengths  
The Quanta System Diode Medical Lasers Family, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic

surgery.

The Quanta System Diode Medical Lasers Family are indicated for use in the performance of specific surgical applications in gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic surgery as follows:

**Gastroenterology (Medical 30)**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gastroenterology procedures. Applications include: hemostasis of esophageal varices; palliation of malignant dysphagia; palliative ablation of obstructive neoplasms; hemostasis of colonoscopy.

**Neurosurgery (Medical 30, 6)**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in neurosurgery procedures. Applications include: tumors adjacent to the spinal cord; tumors adjacent to the cortex.

**General Surgery (Medical 30)**

Treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein. The ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include: Laparoscopic: appendectomy; cholecystectomy; bowel resection. Open: mastectomy; reduction mammoplasty; breast biopsy; rectal and anal hemorrhoidectomy; bowel resection; colectomy; cholecystectomy; liver resection; condyloma; thyroidectomy; thoracotomy; cavernous hemangioma.

**Genitourinary (Urology) (Medical 30)**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in genitourinary (urology) procedures. Applications include: Transurethral: transurethral incision of the prostate (TUIP); bladder tumors; bladder neck incisions; urethral strictures; exterior sphincterotomy. Laparoscopic lymphadenectomy. Open: condyloma; circumcision; benign and

malignant lesions of external genitalia

Thoracic Surgery (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include: pulmonary resection; coagulation of blebs and bullae; adhesiolysis; pericardiectomy; mediastinal and thoracic lesions and abnormalities; mediastinal lymph node dissection; hemostasis; thoracotomy.

Gynecology (GYN) (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include: Laparoscopic excision/lysis of adhesions; endometrial lesions, including ablation of endometriosis; laparoscopic assisted hysterectomy (LAVH); laser uterosacral nerve ablation (LUNA); myomectomy; ovarian cystectomy; ovarian drilling; tubal fimbrioplasty; appendectomy. Open: 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. Intrauterine: Fibroids/polyps/adhesions; Resection of septum.

Pulmonology (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include: tracheal bronchial lesions.

Ophthalmology (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include: Oculoplastics; open DCR; endo-nasal DCR; tumor excision and biopsy; eyelid reconstruction; blepharoplasty.

Orthopedics (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures. Applications include: Open: Dissect and coagulate.

Otolaryngology (ENT) (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include: Nasal/Sinus: turbinectomy and turbinate reduction/ablation; polypectomy of nose and nasal passages; ethmoidectomy; meatal antrostomy; Laryngo-tracheal: removal of vocal cord/fold nodules, polyps and cysts; arytenoidectomy; tracheal stenosis; Oropharyngeal: uvulopalatoplasty (LAUP, laser UTPP); tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil; hemiglossectomy; Head & Neck: tumor resection on oral, subfacial and neck tissues; parathyroidectomy; thyroidectomy.

In addition, at 808 nm and 940 nm wavelengths, the Quanta system Diode Medical Laser Family is intended for the following use:

Urology (Medical 30):

Lesions of external genitalia; Circumcision; Condyloma; Bladder tumors; Bladder neck incisions; Vaporization of the prostate

Neurosurgery (Medical 30):

Percutaneous Disc Decompression; Discectomy; Hemostasis in conjunction with meningiomas

Arthroscopy (Medical 30):

Chondromalacia; Synovectomy; Meniscectomy

Pulmonary Surgery (Medical 30):

Endoscopic pulmonary applications; Tracheal bronchial lesions; Benign and malignant pulmonary or stricture

Cardiac Surgery (Medical 30):

Coagulation and haemostasis of cardiac tissue

Dermatology/Aesthetics (Medical 30):

Photocoagulation of vascular & dermatological lesions of the face and extremities; Photocoagulation of telangiectasia, veinectasias of the legs and face; Treatment of reticular veins and branch varicosities; Pyogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas;

Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Chery angioma, Hemangioma, Port wine stains, angiokeratoma, and benign ipidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.; Dermatology surgery: Condyloma acuminata, warts, small non malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasia and ulcers debridment; Seborrhic keratosis; Mixoid cyst; Papillary varix; Acne treatment; Hair removal of unwanted hair from skin type I-V;

**Plastic Surgery (Medical 30):**

Cut, coagulation & vaporization;  
Blepharoplasty

**Vascular Surgery (Medical 30):**

Endoluminal or endovenus laser surgery for saphenous incompetent veins.

**Dental applications (Medical 30, 6, 4):**

Frenectomy; Frenotomy; Biopsy; Pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening

**808 nm Wavelength**

The Quanta System Diode Medical Laser Family **(Medical 30)** is intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities. The Quanta System Diode Medical Laser Family are indicated for treatment of incompetence and reflux of superficial veins in the lower extremity.

**940 nm Wavelength**

The Quanta System Diode Medical Laser Family **(Medical 30)** is intended for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

The Quanta System Diode Medical Laser Family **(Medical 30)** is intended for use in the treatment of

symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85cc and for cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes and colonoscopes), or in incision/excision, vaporization, ablation and coagulation of soft tissue in contact or non contact open surgery (with or without a handpiece).

It (Medical 30) is also intended for use in the treatment and/or removal of vascular lesions (tumors) and for the removal of unwanted hair.

It (Medical 30) is also indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT and Radiology.

The Quanta System Diode Laser Family (Medical 30, 6, 4) is also indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue including marginal and inter-dental gingival and epithelial lining of free gingival 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; Haemostasis 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

The Quanta System Diode Laser Family (Medical 30, 6, 4) is also indicated for Laser Periodontal procedures, including: Laser soft tissue curettage; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

Model 30 is indicated for Surgical, Dermatological, Dental and Endovascular applications.

Model 6 and Model 4 are indicated for Dental and Surgical applications.

**Technological  
Characteristics:**

The Diode Laser Family is designed with 4 major subsystems: (1) an external structure; (2) power electronics; (3) display with control electronics, which controls the power electronics, the user interface and the laser source temperature via a thermostat board; and (4) the laser system with an opto-mechanical block composed of the laser source, the Peltier cooling system with dissipater and fans, the fiber launching system, the red diode aiming beam, and the power calibration system. The external accessories include separate optical fibers and hand pieces for dental, dermatological and surgical applications, or for endovascular applications. The fiber is connected to the system through an SMA 905 socket on the front panel. In addition to the four subsystems, the Diode Laser Family incorporates several safety features, including a remote interlock and a key switch..

**Substantial  
Equivalence:**

The Quanta System Diode Medical Laser Family is as safe and effective as the predicate devices. The Diode Medical Laser Family has the same intended uses, and similar indications for use, technological characteristics, and principles of operation as the predicates. The minor technological differences between the Diode Medical Laser Family and its predicates raise no new issues of safety or effectiveness. Thus, the Diode Medical Laser Family is substantially equivalent.



FEB 21 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Quanta System, S.P.A.  
c/o Mr. Mark Job  
Regulatory Technology Services, LLC  
1394 25th Street, Northwest  
Buffalo, MN 55313

Re: K072034  
Trade/Device Name: Quanta System Diode Medical Laser Family: Models 4, 6, and 30  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology  
Regulatory Class: II (two)  
Product Code: OCL, GEX  
Dated: August 28, 2007  
Received: August 29, 2007

Dear Mr. Job:

This letter corrects our substantially equivalent letter of September 20, 2007.

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 (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.

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.

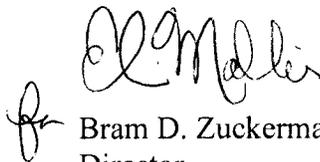
Page 2 - Mr. Mark Job

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known) : \_\_\_\_\_

Device Name:       Quanta System Diode Medical Laser Family:  
                          Models 4, 6, and 30

### Indications For Use:

#### 808 nm, 940 nm, 980 nm Wavelengths

The Quanta System Diode Medical Lasers Family, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic surgery.

The Quanta System Diode Medical Lasers Family are indicated for use in the performance of specific surgical applications in gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic surgery as follows:

#### Gastroenterology (Medical 30)

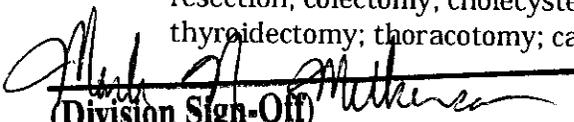
The ablation, vaporization, excision, incision, and coagulation of soft tissue in gastroenterology procedures. Applications include: hemostasis of esophageal varices; palliation of malignant dysphagia; palliative ablation of obstructive neoplasms; hemostasis of colonoscopy.

#### Neurosurgery (Medical 30.6)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in neurosurgery procedures. Applications include: tumors adjacent to the spinal cord; tumors adjacent to the cortex.

#### General Surgery (Medical 30)

Treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein. The ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include: Laparoscopic: appendectomy; cholecystectomy; bowel resection. Open: mastectomy; reduction mammoplasty; breast biopsy; rectal and anal hemorrhoidectomy; bowel resection; colectomy; cholecystectomy; liver resection; condyloma; thyroidectomy; thoracotomy; cavernous hemangioma.

  
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Genitourinary (Urology) (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in genitourinary (urology) procedures. Applications include: Transurethral: transurethral incision of the prostate (TUIP); bladder tumors; bladder neck incisions; urethral strictures; exterior sphincterotomy. Laparoscopic lymphadenectomy. Open: condyloma; circumcision; benign and malignant lesions of external genitalia

Thoracic Surgery (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include: pulmonary resection; coagulation of blebs and bullae; adhesiolysis; pericardiectomy; mediastinal and thoracic lesions and abnormalities; mediastinal lymph node dissection; hemostasis; thoracotomy.

Gynecology (GYN) (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include: Laparoscopic excision/lysis of adhesions; endometrial lesions, including ablation of endometriosis; laparoscopic assisted hysterectomy (LAVH); laser uterosacral nerve ablation (LUNA); myomectomy; ovarian cystectomy; ovarian drilling; tubal fimbrioplasty; appendectomy. Open: 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. Intrauterine: Fibroids/polyps/adhesions; Resection of septum.

Pulmonology (Medical 30)

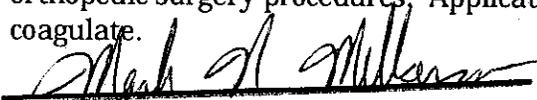
The ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include: tracheal bronchial lesions.

Ophthalmology (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include: Oculoplastics; open DCR; endo-nasal DCR; tumor excision and biopsy; eyelid reconstruction; blepharoplasty.

Orthopedics (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures. Applications include: Open: Dissect and coagulate.



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Otolaryngology (ENT) (Medical 30)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include: Nasal/Sinus: turbinectomy and turbinate reduction/ablation; polypectomy of nose and nasal passages; ethmoidectomy; meatal antrostomy; Laryngo-tracheal: removal of vocal cord/fold nodules, polyps and cysts; arytenoidectomy; tracheal stenosis; Oropharyngeal: uvulopalatoplasty (LAUP, laser UTPP); tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil; hemi glossectomy; Head & Neck: tumor resection on oral, subfacial and neck tissues; parathyroidectomy; thyroidectomy.

In addition, at 808nm and 980nm wavelengths, the Quanta system Diode Medical Laser family is intended for the following use:

Urology (Medical 30):

Lesions of external genitalia; Circumcision; Condyloma; Bladder tumors; Bladder neck incisions; Vaporization of the prostate

Neurosurgery (Medical 30):

Percutaneous Disc Decompression; Discectomy; Hemostasis in conjunction with meningiomas

Arthroscopy (Medical 30):

Chondromalacia; Synovectomy; Meniscectomy

Pulmonary Surgery (Medical 30):

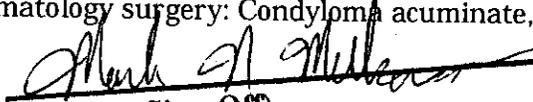
Endoscopic pulmonary applications; Tracheal bronchial lesions; Benign and malignant pulmonary or stricture

Cardiac Surgery (Medical 30):

Coagulation and haemostasis of cardiac tissue

Dermatology/Aesthetics (Medical 30):

Photocoagulation of vascular & dermatological lesions of the face and extremities; Photocoagulation of telangiectasia, veinulectasias of the legs and face; Treatment of reticular veins and branch varicosities; Pyogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas; Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Chery angioma, Hemangioma, Port wine stains, angiokeratoma, and benign ipidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.; Dermatology surgery: Condyloma acuminata, warts, small non malignant



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skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasy and ulcers debridment; Seborrhic keratosis; Mixoid cyst; Papillary varix; Acne treatment; Hair removal of unwanted hair from skin type I-V;

Plastic Surgery (Medical 30):

Cut, coagulation & vaporization; Blepharoplasmy

Vascular Surgery (Medical 30):

Endoluminal or endovenus laser surgery for saphenous incompetent veins.

Dental applications (Medical 30, 6, 4):

Frenectomy; Frenotomy; Biopsy; Pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening

**808 nm Wavelength**

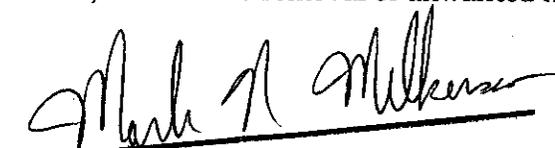
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**940nm Wavelength**

The Quanta System Diode Medical Laser Family (Medical 30) is intended for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

The Quanta System Diode Medical Laser Family (Medical 30), is intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85cc and for cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes and colonoscopes), or in incision/excision, vaporization, ablation and coagulation of soft tissue in contact or non contact open surgery (with or without a handpiece).

It (Medical 30) is also intended for use in the treatment and/or removal of vascular lesions (tumors) and for the removal of unwanted hair.



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It (Medical 30) is also indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT and Radiology.

The Quanta System Diode Laser Family (Medical 30, 6, 4) is also indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue including marginal and inter-dental gingival and epithelial lining of free gingival 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; Haemostasis 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

The Quanta System Diode Laser Family (Medical 30, 6, 4) is also indicated for Laser Periodontal procedures, including: Laser soft tissue curettage; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

Prescription Use: X  
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use:       
(Part 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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