K072564 MAY 23 2008

Section 5 – 510(k) Summary or 510(k) Statement

I. General Information

Submitter:	Alma Lasers, Ltd. Halamish Street (PO Box 3021), Industrial Park, Caesarea, 38900 ISRAEL
Contact Person:	Ziv Karni President, Alma Lasers, Ltd. Tatiana Epstein Regulatory Affairs Manager, Alma Lasers, Ltd.
Summary Preparation Date:	September 3rd, 2007

II. Names

Device Names:	Harmony XL™ Multi-Application Platform
Primary Classification Names:	Surgical Powered Laser Instrument, Ultraviolet Dermatological Light, and LED Phototherapy device

III. Predicate Devices

- K033946 – MSq. Lovely System Models : Lovely I (Aria) & Lovely II (Harmony)
- K04200 – Modified MSq. Family of Lovely Light/Laser Systems, Delivery Devices and Accessories
- K051428 - PhotoMedex, Inc.VTRAC Excimer Lamp System
- K060448 - Lumenis One Family of Systems
- K030342 - Lumenis family of IPL Systems
- K024093 - Lumenis Vasculight System
- K020839 - Lumenis IPL Quantum Family
- K041086 - Palomar StarLux Pulsed Light System
- K033549 - Palomar StarLux Pulsed Light System
- K032460 - Sciton Profile BBL System
- K050679 - Cutera Solera Opus Aesthetic Product
- K003614 - Lumenis LightSheer System
- K053628 - Lumenis LightSheer Duet
- K030186 - Syneron Polaris LV Device
- K052324 - Syneron Polaris LV, LVA Device
- K042630 - SkinCare Technologies, Inc. RevLight Device

K072564

- K982546 - Diomedics Inc. Pain-X-2000 Models
- K041879 - Palomar Lux1064 Device
- K043429 - Cynosure Cynergy System
- K033176 - Cynosure TriStar Aesthetic Workstation Laser
- K033172 - Candela GentleYAG Family of Laser Systems
- K023954 - Cutera (Altus) CoolGlide Laser System.

IV. Product Description

The Alma Lasers Harmony XL™ Multi-Application Platform is comprised of the following main components:

- The main console unit that incorporates the touch-screen control panel, power supply modules, cooling system, switching module, service panel and isolating transformer.
- Variety of handpieces and attachment accessories.
- Footswitch.

V. Indications for Use

The Alma Lasers Harmony XL™ Multi-Application Platform is intended for use in dermatologic and general surgical procedures.

The Indications for Use of the Harmony XL™ Multi-Application Platform are provided in Section 4 of this submission.

VI. Rationale for Substantial Equivalence

The Alma Lasers Harmony XL™ Multi-Application Platform shares the same indications for use, device operation, technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Alma Lasers Harmony XL™ Multi-Application Platform is substantially equivalent to the predicate devices.

VIII. Conclusion

The Alma Lasers Harmony XL™ Multi-Application Platform was found to be substantially equivalent to the predicate devices.

The Alma Lasers Harmony XL™ Multi-Application Platform shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alma Lasers, Ltd.
% A. Worden Consulting
Ms. Anne Worden
3637 Bernal Avenue
Pleasanton, California 94566

MAY 23 2008

Re: K072564
Trade/Device Name: Harmony XL™ Multi-Application Platform and Thermoelectric Cooler
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX, FTC, HHR, LNK
Dated: April 18, 2008
Received: April 23, 2008

Dear Ms. Worden:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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 begin 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K072564**

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use:

The Harmony XL™ Multi-Application Platform is intended for use in aesthetic, cosmetic, and surgical applications requiring the ablation, vaporization, excision, incision, and photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of dermatology, general and plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, oral surgery, ophthalmology (skin around the eyes), orthopedics, pulmonary/thoracic surgery, and urology for surgical and aesthetic applications, as follows:

DERMATOLOGY AND PLASTIC SURGERY

Harmony XL™ Multi-Application Platform:

300-380 nm UVB Module Handpiece

The 300-380 nm UVB module handpiece is indicated for:

- The treatment of leukoderma, including vitiligo (acquired leukoderma).
- The treatment of psoriasis, atopic dermatitis (eczema), and seborrheic dermatitis.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): K072564

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

DERMATOLOGY AND PLASTIC SURGERY - continued

Harmony XL™ Multi-Application Platform:

420-950 nm Acne Module AFT Handpiece

The Advanced Fluorescence Technology (AFT) 420-950 nm Acne Module handpiece (with and without contact-cooling) is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- Use on all skin types (Fitzpatrick I-VI).

515-950 nm SV515 & SVL515 Module AFT Handpieces

The Advanced Fluorescence Technology (AFT) 515-950 nm VL515 and SVL515 Module handpieces (with and without contact-cooling) are indicated for:

- The treatment of moderate inflammatory acne (acne vulgaris).
- The treatment of tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars, striae, dyschromia, hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction.
- Use on Fitzpatrick skin types I-V.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): **K072564**

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use - Continued:

DERMATOLOGY AND PLASTIC SURGERY - Continued

Harmony XL™ Multi-Application Platform - Continued:

540-950 nm VL/PL, VP, and SSR Module AFT Handpieces

The Advanced Fluorescence Technology (AFT) 540-950 nm VL/PL, VP, and SSR Module handpieces (with and without contact-cooling) are indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules.
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction.
- Use on all skin types (Fitzpatrick I-VI).

570-950 nm SR Module AFT Handpiece

The Advanced Fluorescence Technology (AFT) 570-950 nm SR Module handpiece (with and without contact-cooling) is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles).
- The treatment of face and body vascular and pigmented lesions.
- The treatment of cutaneous lesions, including scars and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction.
- Use on all skin types (Fitzpatrick I-VI).

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): K072564

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use - Continued:

DERMATOLOGY AND PLASTIC SURGERY - Continued

Harmony XL™ Multi-Application Platform - Continued:

590 nm LED Module Handpiece

The 590 nm LED module handpiece is indicated to:

- Provide topical heating to promote increased blood flow for temporary relaxation of muscle and relief of pain.
- Provide topical heating for the purpose of elevating and/or maintaining tissue temperature.

650-950 nm HR Module AFT Handpiece

The Advanced Fluorescence Technology (AFT) 650-950 nm HR Module handpiece (with and without contact-cooling) is indicated for:

- The treatment of tattoos.
- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait.
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Neil R P Ogden for Mark

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Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): **K072564**

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use - Continued:

DERMATOLOGY AND PLASTIC SURGERY - Continued

Harmony XL™ Multi-Application Platform - Continued:

780-950 nm SHR and ST AFT Module Handpieces

The Advanced Fluorescence Technology (AFT) 780-950 nm SHR and ST Module handpieces (with and without contact-cooling) are indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The treatment of pseudofolliculitis barbae (PFB).
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): K072564

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use - Continued:

DERMATOLOGY AND PLASTIC SURGERY - Continued

Harmony XL™ Multi-Application Platform - Continued:

780-950 nm SST AFT Module Handpiece

The Advanced Fluorescence Technology (AFT) 780-950 nm SST Module handpiece (with contact-cooling) is indicated for:

- The treatment of tattoos.
- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis.
- The treatment of pseudofolliculitis barbae (PFB).
- The removal of unwanted hair to effect stable long-term or permanent hair reduction
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MKN

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Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): K072564

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

DERMATOLOGY AND PLASTIC SURGERY - continued

Harmony XL™ Multi-Application Platform:

1064 nm Long Pulsed and Q-Switched Nd:YAG Laser Module Handpieces

The 1064 nm Nd:YAG Laser Module handpieces (Long Pulsed and Q-Switched with and without contact-cooling) are indicated for treatment and clearance of:

- Benign vascular lesions such as, but not limited to treatment of:
  - Port wine stains
  - Hemangiomas
  - Warts
  - Superficial and deep telangiectasias (venulectasias)
  - Reticular veins (0.1-4.0 mm dia.) of the leg
  - Rosacea
  - Venus lake
  - Leg veins
  - Spider veins
  - Poikiloderma of Civatte
  - Angiomas
- Benign cutaneous lesions, such as, but not limited to:
  - Warts
  - Scars
  - Striae
  - Psoriasis

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

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Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): K072564

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

DERMATOLOGY AND PLASTIC SURGERY - continued

Harmony XL™ Multi-Application Platform:

1064 nm Long Pulsed and Q-Switched Nd:YAG Laser Module Handpieces - continued
The 1064 nm Nd:YAG Laser Module handpieces (Long Pulsed and Q-Switched, with and without contact-cooling) – continued:

- Benign pigmented lesions such as, but not limited to:
  - Lentigos (age spots)
  - Solar lentigos (sun spots)
  - Café-au-lait macules
  - Seborrheic keratoses
  - Nevi and nevus of Ota
  - Chloasma
  - Verrucae
  - Skin tags
  - Keratoses
  - The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos).
  - Plaques

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R? Ogle for MAC

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): **K072564**

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

DERMATOLOGY AND PLASTIC SURGERY - continued

Harmony XL™ Multi-Application Platform:

1064 nm Long Pulsed and Q-Switched Nd:YAG Laser Module Handpieces - continued
The 1064 nm Nd:YAG Laser Module handpieces (Long Pulsed and Q-Switched, with and without contact-cooling) – continued:

- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to:
  - Periocular wrinkles
  - Perioral wrinkles
- Laser skin resurfacing procedures for the treatment of:
  - Acne scars
  - Wrinkles
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

1064 nm Long Pulsed Only Nd:YAG Laser Module Handpieces
The 1064 nm Nd:YAG lasers (Long Pulsed only, with and without contact-cooling) is indicated for:

- Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles.
- Removal or lightening of unwanted hair (with and without adjuvant preparation)
- Treatment of pseudofolliculitis barbae (PFB)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): **K072564**

Device Name: Harmony XL™ Multi-Application Platform

DERMATOLOGY AND PLASTIC SURGERY - continued

Harmony XL™ Multi-Application Platform:

532 nm Long Pulsed and Q-Switched FD Nd:YAG Laser Module Handpiece Tips

The 532 nm Frequency-Doubled (FD) Nd:YAG Laser Module handpieces tips (Long Pulsed and Q-Switched, with and without contact-cooling) are indicated for:

- Incision, excision, ablation, vaporization of soft tissue.
- Tattoo removal
  - Light blue
  - Yellow
  - Red
  - Green
- Vascular lesions
  - Hemangiomas (Port wine stains/birthmarks, cavernous, cherry, spider) hemangiomas)
  - Angiomas (cherry, spider)
  - Telangiectasia
  - Spider nevi

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Neil R P Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): **K072564**

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

DERMATOLOGY AND PLASTIC SURGERY - continued

Harmony XL™ Multi-Application Platform:

532 nm Long Pulsed and Q-Switched FD Nd:YAG Laser Module Handpiece Tips - continued

The 532 nm Frequency-Doubled (FD) Nd:YAG Laser Module handpiece tips (Long Pulsed and Q-Switched, with and without contact-cooling) are indicated for:

- Benign pigmented lesions
  - Café-au-lait (macules)
  - Lentigines (senile and solar)
  - Freckles (ephelides)
  - Chloasma
  - Nevi
  - Nevus spillus
  - Nevus of Ota
  - Becker's Nevi
- Other pigmented cutaneous lesions
  - Verrucae
  - Skin tags
  - Keratoses
  - Plaques

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): **K072564**

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

DERMATOLOGY AND PLASTIC SURGERY - continued

Harmony XL™ Multi-Application Platform:

1320 nm Nd:YAG Laser Module Handpiece

1320 nm Nd:YAG Laser Module handpiece (with and without contact-cooling) is indicated for the treatment of:

- Fine lines and wrinkles
- Periorbital wrinkles
- Perioral wrinkles
- Back acne
- Atrophic acne scars
- Mild to moderate inflammatory acne vulgaris

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for MKN

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): **K072564**

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

DERMATOLOGY AND PLASTIC SURGERY - continued

Harmony XL™ Multi-Application Platform:

2940 nm Er:YAG Laser Module Handpiece with Standard & Scanner Accessory Tips

The 2940 nm Er:YAG Laser Module handpiece with standard and scanner accessory tips (with and without contact-cooling) is indicated for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands:

DERMATOLOGY AND PLASTIC SURGERY:

- Skin resurfacing
- Treatment of wrinkles
- Epidermal nevi
- Telangiectasia
- Spider veins
- Actinic chelitis
- Keloids
- Verrucae
- Skin tags
- Anal tags
- Keratoses
- Scar revision (including acne scars)
- Debulking benign tumors
- Debulking cysts
- Superficial skin lesions
- Diagnostic biopsies
- Decubitus ulcers

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): K072564

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

Harmony XL™ Multi-Application Platform:

2940 nm Er:YAG Laser Module Handpiece with Standard & Scanner Accessory Tips - Continued

GENERAL SURGERY:

- Surgical incision/excision, vaporization, ablation, and coagulation of soft tissue where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation, and/or vessel coagulation may be indicated.

GENITOURINARY:

Treatment of:

- Lesions of the external genitalia, urethra and anus, penis, scrotum, and urethra (includes condyloma acuminate, giant perineal condyloma, and verrucous carcinoma), vulvar lesions, polyps, and familiar polyps of the colon.

GYNECOLOGY:

Treatment of:

- Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts, and condyloma.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MAN

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): K072564

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

Harmony XL™ Multi-Application Platform:

2940 nm Er:YAG Laser Module Handpiece with Standard & Scanner Accessory Tips - Continued

ORAL/MAXILLOFACIAL:
Treatment of:
- Benign oral tumors, oral and glossal lesions, and gingivectomy.

OTORHYNOLARINGOLOGY/HEAD AND NECK (ENT):
Treatment of:
- Ear, nose and throat lesions, polyps, cysts, hyperkeratosis.
- Excision of carcinogenic tissue and oral leukoplakia.

OPHTHALMOLOGY:
Treatment of:
- Soft tissue surrounding the eye and orbit.

PODIATRY:
Treatment of:
- Warts, plantar verrucae, large mosaic verrucae.
- Matrixectomy.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072564

Indications for Use Statement

510(k) Number (if known): K072564

Device Name: Harmony XL™ Multi-Application Platform

Indications for Use: - Continued from previous page -

Harmony XL™ Multi-Application Platform:

2940 nm Er:YAG Laser Module Handpiece with Pixel Accessory Tips

The 2940 nm Er:YAG Laser Module handpiece (with and without contact-cooling) with Pixel accessory tips is indicated for use in soft tissue for:

DERMATOLOGY AND PLASTIC SURGERY:

- Skin resurfacing

Thermoelectric Cooler (TEC)

The thermoelectric cooler, integrated into the light and laser handpieces, is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:

- Reduce pain during and/or associated with light or laser treatment;
- Reduce discomfort during and/or associated with light or laser treatment;
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
- Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and
- Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkn

(Division Sign-Off)

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