



Food and Drug Administration  
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Quanta System SPA  
Mr. Francesco Dell'Antonio  
Compliance Manager  
Via IV Novembre, 116  
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Italy

September 3, 2015

Re: K152220

Trade/Device Name: MH01

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: July 23, 2015

Received: August 7, 2015

Dear Mr. Dell'Antonio:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joshua C. Nipper -S**

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

For

Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152220

Device Name

MH01

Indications for Use (Describe)

The MH01 laser system, including a fiber optic delivery system, is indicated for use in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and in Lithotripsy of stones.

It is indicated in medical specialties including, but not limited to:

- Urology
- Gastroenterology
- Arthroscopy
- Neurosurgery
- Pulmonary
- Gynecology
- ENT
- Dermatology
- Plastic Surgery
- General Surgery

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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## 5. Special 510(K) SUMMARY – Device Modifications

### Introduction:

This document contains the 510(k) Summary for the device MH01.  
The basis of this submission is Modifications to Device already cleared.  
The content of this summary is based on the requirements of 21 CFR 807.92(c).

**Applicant /  
Manufacturer  
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**Date Prepared:** July 23<sup>th</sup>, 2015

**Device Name:** MH01

**Classification:** Class II

**Classification Name:** Laser surgical instrument for use in general and plastic surgery  
and in dermatology.

**Regulation Number:** 21 CFR 878.4810

**Product Code:** GEX

**Basis for Submission:** Device modifications

**Legally Marketed Device** Litho DK30 (K141403) – Quanta System SPA

The modified device MH01 is claimed to be derived from the legally marketed (unmodified) device Litho DK30 (K141403) because MH01 is the tower version of the already cleared device Litho DK30 (K141403) with modified graphic user interface.

### Performance Standards:

This device complies with 21 CFR 1040.10 and 1040.11.

### **General Device Description:**

This Special 510(k) of the modified device MH01 is submitted due to Device Modifications of the already cleared device Litho DK30 (K141403Q): MH01 differs from Litho DK30 (K141403Q) about:

- housing of components: tower frame instead of desktop
- graphic user interface

The modified device MH01 has the same intended use of the unmodified device. Moreover the the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

The modified and unmodified devices have the same components, the same laser source emission specifications and the same controlling principles.

Both devices are Pulsed Holmium:YAG laser with a maximum output power of 30 W @ 2.1  $\mu\text{m}$ .

There are not incremental changes from the original clearance K141403Q to be taken into account other than the differences between modified and unmodified devices.

### **Description of the modifications:**

The modified device MH01 shares the same architecture and the same laser source of the unmodified device Litho DK30: both devices are Pulsed Holmium:YAG laser with a maximum output power of 30 W @ 2.1  $\mu\text{m}$ , with no change in the fundamental scientific technology of the device.

The modified device MH01 has the same intended use of the unmodified device. Moreover the intended use of the modified device, as described in its labelling, has not changed as a result of the modifications.

The following modifications have been implemented on the cleared device Litho DK30 (K141403) in order to get the tower version named MH01:

- A new mechanical structure housing the internal components, and related covers have been developed
- The GUI (Graphic User Interface) has been reviewed

Based on the nature of the changes implemented, the device underwent and successfully passed EMC, electrical safety and performance testing according to IEC 60601-1 and its collateral standards.

Picture 7-1 shows the external appearance of the modified device and the unmodified device.



Picture 5-1 – device Litho DK30 (on the left) and MH01 (on the right)

### **Intended Use/Indications for Use**

The modified device MH01 has the same intended use of the unmodified device, as follows:

The MH01 laser system, including a fiber optic delivery system, is indicated for use in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and in Lithotripsy of stones.

It is indicated in medical specialties including, but not limited to:

- Urology
- Gastroenterology
- Arthroscopy
- Neurosurgery
- Pulmonary
- Gynecology
- ENT
- Dermatology
- Plastic Surgery
- General Surgery

Moreover the intended use of the modified device, as described in its labelling, has not changed as a result of the modifications.

### **Substantial Equivalence:**

The modified and unmodified devices have the same components, the same laser sources with the same emission specifications and the same controlling principles.

The modified device MH01 has the same intended use of the unmodified device.

Thus the modified device MH01 is substantially equivalent to the previously legally marketed device Litho DK30 (K141403).

### **Performance testing**

The modified device MH01 was subjected to performance testing in accordance with the following recognized consensus standards related to electromagnetic compatibility, electrical safety and performances:

- IEC 60601-1:2005, Mod - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- IEC 60601-2-22 Third Edition 2007-05, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment
- IEC 60825-1 Edition 2.0 2007-03, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements

The modified device MH01 passed all the required testing and is in compliance with all applicable sections of the above mentioned performance standards.