DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 19, 2017

Patient Pocket LLC
% Ray Kelly
Consultant
Licensale, Inc.
68 Southwoods Terrace
Southbury, Connecticut 06488

Re: K170215
Trade/Device Name: LaserDock, HolmiumDock, CO2Dock, OmniDock, KTPDock
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: January 15, 2017
Received: January 24, 2017

Dear Ray Kelly:

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" (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 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,

Jennifer R. Stevenson -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170215

Device Name

LaserDock (HolmiumDock, CO2Dock, OmniDock, KTPDock)

Indications for Use *(Describe)*

LaserDock is indicated to hold laser fibers and prevent any unwanted laser emissions from escaping LaserDock. The LaserDock is designed for use with Ho:YAG ("HolmiumDock"), Nd:YAG, CO2 ("CO2Dock", OmniDock"), and KTP ("KTPDock") laser systems when laser fibers are deployed.

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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Section 003
510k Summary

This 510(k)-summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Patient Pocket LLC 405 Hialeah Dr Cherry Hill, NJ 08002
DATE PREPARED:	April 18, 2017
CONTACT PERSON:	Raymond Kelly
TRADE NAME:	LaserDock HolmiumDock CO2Dock OmniDock KTPDock
CLASSIFICATION NAME:	Powered Laser Surgical Instrument
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER	21 CFR 878.4810
PRODUCT CODE	GEX
PREDICATE DEVICES:	LaserDock (K152636)

Substantially Equivalent To:
The LaserDock (HolmiumDock, CO2Dock, OmniDock, KTPDock) is substantially equivalent in intended use, principal of operation and technological characteristics to the previously cleared LaserDock (K152636).

Description of the Device Subject to Premarket Notification:
The LaserDock is a sterile holster accessory to be used with surgical lasers and fiber optic laser energy delivery devices (laser fibers). The FDA recognizes that laser fibers can pose a risk of surgical fires, patient burns, and injuries if they are not properly secured. As part of a broader surgical fire prevention initiative, the FDA recommends that ignition sources such as ESUs (laser fibers) be placed "in a holster, and not on the patient or drapes," when not in use. [[1]]

[1] Preventing Surgical Fires: FDA Safety Communication (Oct. 3, 2011).

The LaserDock can be marketed under the following brand names (HolmiumDock, CO2Dock, OmniDock, or KTPDock). During a clinical procedure, when the laser fiber is not deployed in the patient, insertion into the LaserDock provides a sterile and secure holster for temporarily protecting the laser fiber. The sterility of the laser fiber is maintained by the sterile LaserDock.

The LaserDock is a single use sterile device comprising of an inner medical grade silicone tube, a clamp for securing the laser fiber in place, and a clam shell housing to protect the inner silicone tubing. When not in use, the laser fiber is held securely within the sterile medical grade silicone tubing by a twist clamp. Upon insertion of the laser fiber into the Laserdock, accidental discharging of laser energy is prevented from escaping the LaserDock and injuring or burning users and patients or creating potential fire hazards within the sterile field or outside of the sterile field.

Indications for Use

LaserDock is indicated to hold laser fibers and prevent any unwanted laser emissions from escaping LaserDock. The LaserDock is designed for use with Ho:YAG ("HolmiumDock"), Nd:YAG, CO2 ("CO2Dock", OmniDock"), and KTP ("KTPDock") laser systems when laser fibers are deployed.

Technological Characteristics:

The modified LaserDock has the same technological characteristics and is similar in design and performance compared to the previously cleared device.

Both the predicate and proposed LaserDock have a sterile chamber where the fiber wire is secured preventing it from becoming contaminated or exposed to non-sterile surfaces, it also protects it within a hard shell from being crimped or damaged or falling on the floor where it can be stepped on. The retention clamp secures the fiber wire firmly within the protective sterile chamber without damaging the fiber.

Both the predicate and proposed LaserDock are made from a medical grade ABS housing which contains an internal medical grade silicone tube. Although the device does not have patient contact the device is made from the highest medical grade materials and provided sterile.

Both the predicate and proposed LaserDock have a retention clamp to keep the fiber wire securely inside the protective housing and sterile tube.

Performance Data

Testing conducted on the LaserDock demonstrates the modified device is substantially equivalent to the previously cleared LaserDock.

Basis for Determination of Substantial Equivalence:

Upon reviewing and comparing intended use, design, principle of operation and overall technological characteristics, the LaserDock is determined by Patient Pocket LLC., to be substantially equivalent to the existing legally marketed device LaserDock.

Sterile Protective Enclosure

Both the predicate LaserDock and the proposed LaserDock are single use devices which are terminally sterilized to achieve an SAL 10^{-6}. Both devices are packaged in a validated environmental barrier package which protects the sterility of the device until it is opened for use. Both the predicate and proposed LaserDock are intended to be opened and used within a sterile surgical field to prevent the device from becoming contaminated. Both devices have been validated for package integrity, shelf life validation, and sterility. The gamma sterilization validation followed the overkill method and consisted of a VDMax validation and the package was validated using peel tests and bubble emersion tests on the pouches.

Biocompatible Material

Both the predicate and proposed LaserDock are made from a medical grade ABS housing and an internal medical grade silicone tube. Both the predicate and the proposed LaserDock have been validated to be biocompatible for cytotoxicity, systemic toxicity, irritation, sensitization, and material mediated pyrogen.

Fiber Wire Securement

Both devices have been tested to validate the pull force to ensure the fiber does not become dislodged from the LaserDock if it is accidentally tugged by the users. Based on these treatment types the following laser fibers will be used 200-500µm, 500-1000µm, and 1-2.1mm. We have based the largest force parameter (5 lb/f) based on the largest fiber intended to be used which is the KTP green light 180 moxy fiber and the smallest force parameter (1 lb/f) based on the smallest fiber intended to be used (200µm) and on the maximum grip users can get with a wet glove which is 0.7 lb/f.

- – 5 lb/f for fiber diameters between 200 – 500 µm
- 2 - 5 lb/f for fiber diameters between 500 – 1000 µm
- 2 - 5 lb/f for fiber diameters between 1 – 2.1 mm

All pull testing passed for both the predicate and proposed LaserDock.

Accidental Laser Fiber Suppression

The device holds the fiber securely in place to prevent practitioners from attaching the fiber to the patient's lower extremity drape or from placing instruments on top of the laser fiber potentially damaging the fiber ("ANSI Z136-3, Safe Use of Lasers in Hospital Facilities".) The Laser Dock has a containment area (tubing) within the device to absorb the wavelength if the laser is accidently fired during the procedure. The outer shell of the device is the housing and the inner containment tubing acts as a heat sink to dissipate any thermal buildup that may occur from accidental activation of the laser. Testing of the Laser Dock consisted of live firing into the device for 10 seconds (worst case scenario) to test the Laser Dock ability to withstand direct laser energy. The decision to use

the 10 second time frame as “worst case” revolves around a combination of field experience and the maximum permissible exposure (MPE) for the referenced wavelengths as outlined in ANSI Z136.3, Appendix A and ISO 11810-1/11810-2. Validation testing was performed initially on Ho:YAG, Nd:YAG, and KTP Diode Lasers.

Wavelength	Mode	Max Power	Exposure Time
532nm	Continuous	30 Watts	10s
980nm	Continuous	180 Watts	10s
1064nm	Continuous	100 Watts	10s
2100nm	Pulsed	100 Watts	10s

Testing results all met acceptance criteria in that the containment material showed no visual signs of exposure stress after being exposed to each of the four wavelengths at maximum power and maximum exposure times. The outer shell does not have any heat transferred to it because the inner protective tubing blocks all heat, energy, and penetration of the laser energy.

Primary and Secondary Ignition and Penetration

Fire safety and penetration safety testing was performed following ISO 11810-1:2005 and ISO 11810-2:2007 for both safety of primary ignition and secondary ignition and for penetration. The worst-case laser type intended to be used with the device is CO2, therefore all laser firing was performed at this stage on the CO2 laser fibers. CO2 has been selected as the most hazardous energy type for causing potential damage or fire risk to the Laser Dock. CO2 is a more aggressive energy type then the other energy types which Laser Dock is intended to safely block, including Ho:YAG, Nd:YAG, and KTP laser systems due to its higher output temperatures and the fact that CO2 has a narrower focused diameter at the output. The narrower focused diameter and higher output temperature creates a higher intensity energy point compared to other types, making it the worst case energy type for containment and highest risk for ignition source, and therefore it was chosen to represent the other intended energy types for this study (Ho:YAG, Nd:YAG, and KTP). Testing was performed using CO2 with a 20-watt intensity for firing periods of 10 seconds. Spot diameter on target was 2mm. Primary ignition testing was performed on the test articles per ISO to establish classification for ignition.

All samples were tested for primary ignition risk and were classified as Class I1 material, material does not ignite after 10 seconds of focused laser contact. Material is safe and does not present a risk as a primary ignition source. All samples were tested for secondary ignition risk and were classified as Class SI1 material, material does not ignite after 10 seconds of focused laser contact, and gauze does not ignite after 10s of energy contact. Material is safe and does not present a risk as a primary ignition source. All samples were tested for penetration risk and were classified as Class P1 material, no penetration observed after 10 seconds of focused laser contact. Material is safe and does not present a risk for penetration.