November 24, 2025

Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
Zhengzhou Li
Official Correspondent
Room 208, Building C, No. 3, Juquan Road,
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K252771
Trade/Device Name: Holmium Laser System (Potent HP90); Holmium Laser System (Potent HP100); Holmium Laser System (Potent HP9120); Holmium Laser System (Potent HP140); Holmium Laser System (Potent HP150)
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: September 2, 2025
Received: September 2, 2025

Dear Zhengzhou Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.11.24 15:30:30 -05'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252771

Device Name
Holmium Laser System (Potent HP90); Holmium Laser System (Potent HP100); Holmium Laser System (Potent HP9120); Holmium Laser System (Potent HP140); Holmium Laser System (Potent HP150)

Indications for Use *(Describe)*

The Holmium laser system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Gynecology, ENT and 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
#K252771

1 Submitter / Contact Information

Field	Information
Date Preparation	November 24, 2025
Submitter Name	Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
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Contact Person	Zhengzhou Li
Email	potent_medical_public@potent-medical.com

2 Device Information

Field	Information
Device Trade Name	Holmium Laser System
Models	Potent HP90, Potent HP100, Potent HP120, Potent HP140, Potent HP150
Common Name	Powered Laser Surgical Instrument
Regulation Name	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulation Number	21 CFR 878.4810
Regulatory Class	Class II
Product Code	GEX
Panel	General and Plastic Surgery

3 Predicate and Reference Devices

Type	Device	Manufacturer	510(k) Number
Primary Predicate	Litho 150 / Cyber Ho 150 Holmium Laser System	Quanta System S.p.A.	K201455
Reference Device	MultiPulse HoPlus Holmium Laser System	Asclepion Laser Technologies GmbH	K161257

4 Device Description

The Potent HP Series is a family of pulsed solid-state Holmium:YAG laser systems that deliver energy at a wavelength of 2100 nm through optical fibers for soft tissue surgery and stone fragmentation. The system utilizes a flashlamp-pumped Ho:YAG laser medium, and the laser energy is transmitted to the target site via SMA905-compatible optical fibers. All models in the series share the same fundamental design and operational principles, differing in maximum average power output and frequency .

The system includes a touchscreen interface, dual-pedal footswitch, fiber auto-recognition, integrated liquid cooling, and multiple built-in safety features such as an emergency stop, door interlock, and real-time monitoring of laser output.

5 Intended Use

The Holmium laser system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue in use in medical specialties including:

- Urology
- Urinary Lithotripsy
- Gastroenterology
- Arthroscopy
- Discectomy
- Gynecology
- ENT
- General surgery

6 Comparison of Technological Characteristics

Feature	**Subject Device (Potent HP Series)**	**Main Predicate (Litho 150 / Cyber Ho 150)**	**Reference Device (MultiPulse HoPlus)**
510(k) No.	/	K201455	K161257
Manufacturer	Potent Medical	Quanta System S.p.A.	Asclepion Laser Technologies GmbH
Regulation	21 CFR 878.4810	Same	Same

Classification	Class II	Class II	Class II
Product Code	GEX	GEX	GEX
Panel	General & Plastic Surgery	Same	Same
Indications for Use	The Holmium laser system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Gynaecology, ENT and General Surgery.	Same	Same + adds pulmonary, dermatology, plastic surgery
Laser Source	Pulsed Ho:YAG (CHT:YAG)	Same	Same
Wavelength	2100 nm	2100 nm	2100 nm
Emission Mode	Pulsed	Pulsed	Pulsed
Pulse Duration	Up to 1700 µs	Up to 1100 µs	Up to 1700 µs
Pulse Energy	Up to 6.0 J	Up to 5.0 J	Up to 6.0 J
Frequency	Up to 120 Hz	Up to 100 Hz	Up to 100 Hz
Max Avg. Power	90–150 W (model dependent)	152 W	140 W
Delivery System	SMA905 optical fibers	Optical fibers	Optical fibers
Aiming Beam	Green diode < 3 mW	Green diode < 5 mW	Green diode < 5 mW
Cooling	Closed-loop liquid	Closed-loop liquid	Closed-loop liquid
Safety Systems	Key switch, door interlock, emergency stop, fiber detection, output monitoring	Equivalent	Equivalent

Conclusion:

The Potent HP Series falls within the same technological range as both predicate devices. Differences in frequency, pulse duration range, and aiming beam intensity do

not raise new questions of safety or effectiveness and are supported by performance testing and risk analysis.

7 Non-Clinical Performance Data

The Potent HP Series Holmium Laser System has undergone comprehensive performance testing to ensure compliance with applicable international standards and FDA guidance. The following evaluations were conducted:

7.1 Electrical Safety and Electromagnetic Compatibility

The device was tested and found to conform to the following standards:

- **IEC 60601-1:2005 + A1:2012 + A2:2020**

  Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- **IEC 60601-1-2:2014 + A1:2020**

  Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.

- **IEC 60601-2-22:2019**

  Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment.

- **IEC 60825-1:2014**

  Safety of laser products – Part 1: Equipment classification and requirements.

7.2 Software Verification and Validation

Software development and validation were performed in accordance with:

- **IEC 62304:2006 + A1:2015**

  Medical device software – Software life cycle processes.

- **FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005).**

8 Substantial Equivalence Conclusion

The Potent HP Series Holmium Laser System has the same intended use and similar technological characteristics as the predicate device. Minor differences between the subject and predicate device do not raise new risks regarding safety or effectiveness.The subject device is **substantially equivalent** to the identified predicate device.