January 24, 2026

Guangzhou Potent Medical Equipment Joint-Stock Co. , Ltd.
Zhengzhou Li
General Manager
Rm. 208, Bldg. C, # 3, Juquan Rd.
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K253633
Trade/Device Name: Holmium Laser Therapeutic Apparatus (HZ-40)
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: November 14, 2025
Received: November 19, 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: 2026.01.24 09:12:14 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253633

Please provide the device trade name(s).

Holmium Laser Therapeutic Apparatus (HZ-40)

Please provide your Indications for Use below.

Holmium Laser Therapeutic Apparatus are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and stone fragmentation in use in medical specialties including: Urology, Gastroenterology, ENT, Gynecology and general surgery.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary - K253633

1 Submitter / Contact Information

Item	Information
Submitter Name	Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
Address	Room 208, Building C, No. 3 Juquan Road, Huangpu District, Guangzhou, Guangdong, 510000, China.
Phone	+86 -20-37396970
Fax	+86 -20-37376979
Contact Person	Zhengzhou Li
Email	potent_medical_public@potent-medical.com
Date	January 23, 2026

2 Subject Device Information

Item	Information
Device Trade Name	Holmium Laser Therapeutic Apparatus
Models	HZ-40
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
Review Panel	General and Plastic Surgery

3 Predicate Devices

Type	Device	Manufacturer	510(k) Number
Primary Predicate Device	Litho DK30	Quanta System SPA	K141403
Secondary Predicate Device	MultiPulse HoPlus(1911)	Asclepion Laser Technologies Gmbh	K161257

4 Device Description

The HZ-40 Holmium Laser Therapeutic Apparatus 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.

The system includes a touchscreen interface, single-pedal footswitch, 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

Holmium Laser Therapeutic Apparatus are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and stone fragmentation in use in medical specialties including: Urology, Gastroenterology, ENT, Gynecology and general surgery.

6 Indications for use

Holmium Laser Therapeutic Apparatus are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and stone fragmentation in use in medical specialties including: Urology, Gastroenterology, ENT, Gynecology and general surgery.

7 Comparison of Technological Characteristics

Device	Subject device	Primarily Predicate device	Secondary Predicate device	Remark
510(k) number	Pending	K141403	K161257	/
Trade name	Holmium Laser Therapeutic Apparatus	Litho DK30	MultiPulse HoPlus	/
Model	HZ-40	/	1911	/
Manufacturer	Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.	Quanta System SPA	Asclepion Laser Technologies Gmbh	/
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Regulation Name	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Same
Regulation Class	Class II	Class II	Class II	Same
Product Code	GEX	GEX	GEX	Same

Device	Subject device	Primarily Predicate device	Secondary Predicate device	Remark
510(k) number	Pending	K141403	K161257	/
Device Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Intended use	Holmium Laser Therapeutic Apparatus are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and stone fragmentation in use in medical specialties including: Urology, Gastroenterology, ENT, Gynecology and general surgery.	The device Litho including a fiber optic delivery system is intended to be used 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.	The MultiPulse HoPLUS Laser system and its fiber optic delivery 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, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.	Similar **Note 1**
Indications for use	Holmium Laser Therapeutic Apparatus are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and stone fragmentation in use in medical specialties including: Urology,	The device Litho including a fiber optic delivery system is indicated for use in surgical proceduressuch as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation.vaporization, coaaulation and hemostasis of soft tissue and in Lithotripsy of	Incision, excision, resection, ablation, vaporisation, coagulation and hemostasis in medical specialties.	Similar **Note 1**

Device	Subject device	Primarily Predicate device	Secondary Predicate device	Remark
510(k) number	Pending	K141403	K161257	/
	Gastroenterology, ENT, Gynecology and general surgery.	stones in medicalspecialties including, but not limited to: Urology, Gastroenterology, Arthroscopy, Neurosurgery, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.		
Laser Source	Pulsed Holmium laser (CHT:YAG)	Pulsed Holmium laser (CHT:YAG)	Pulsed Holmium laser (CHT:YAG)	Same
Wavelength (nm)	2, 100 nm	2, 100 nm	2, 100 nm	Same
Emission	Pulsed	Pulsed	Pulsed	Same
Pulse duration	90-2000μs	Not publicly available	150-1700 μs	Similar **Note 2**
Energy per pulse	0.2-6 J	Not publicly available	0.25-6 Joule	Similar
Frequency	30Hz	Not publicly available	5-100 Hz	Similar **Note 3**
Max average power	40W	30W	140W	Similar **Note4**
Power supply	AC 100-240V, 50/60 Hz, 3.5 kVA	Not publicly available	400 V 50 Hz/16 A 3-phase	Different **Note 5**
Delivery system	Optical fibers	Optical fibers	Optical fibers	Same
Aiming beam	Power < 3mW, Wavelength	Not publicly available	Green diode laser < 5 mW	Similar

Device	Subject device	Primarily Predicate device	Secondary Predicate device	Remark
510(k) number	Pending	K141403	K161257	/
	520nm±10nm, Class 3R			**Note 6**

Note 1:

The intended use and indications for use of the subject device is the same as predicate device(K141403), with only a difference in wording.

Note 2:

The pulse duration of the subject device is similar with the secondary predicate device(K161257), and the energy per pulse of subject device is quite similar with the predicate device, also the subject device has passed the IEC 60601-1 testing and IEC 60601-2-22 testing. So this minor difference of pulse duration will not raise any safety and effectiveness issues.

Note 3:

The frequency of the subject device is within the range of the secondary predicate device(K161257), so this minor difference will not raise any safety and effectiveness issues.

Note 4:

The max average power of the subject device is similar with the primarily predicate device(K141403) and within the range of the secondary predicate device(K161257), also the subject device has passed the IEC 60601-1 testing and the IEC 60601-2-22 testing, so the difference will not raise any safety and effectiveness issues.

Note 5:

Though the power supply of the subject device is different from the predicate devices, the subject device has passed the IEC 60601-1 testing, so the difference will not raise any safety and effectiveness issues.

Note 6:

Though the aiming beam of the subject device is a little different from the predicate device and reference device, the subject device adopted the safer laser and has passed the IEC 60825-1 testing and the IEC 60601-2-22 testing, so this difference will not raise any safety and effectiveness issues.

8 Non-Clinical Performance Data

The HZ-40 Holmium Laser Therapeutic Apparatus has undergone comprehensive performance testing to ensure compliance with applicable international standards and FDA guidance. The following evaluations were conducted:

8.1 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.

8.2 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).

9 Conclusion

Based on the above analysis and non-clinical tests performed, the Holmium Laser Therapeutic Apparatus(Model: HZ-40) has the same intended use/indications for use and similar technological characteristics as the predicate devices. Minor differences between the subject and predicate devices do not raise new risks regarding safety or effectiveness.The subject device is **substantially equivalent** to the identified predicate devices.