March 6, 2026

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

Re: K253951
Trade/Device Name: Holmium Laser Therapeutic Apparatus (HZ-A); Holmium Laser Therapeutic Apparatus (HZ-B); Holmium Laser Therapeutic Apparatus (HZ-E)
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 18, 2025
Received: December 10, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2026.03.06 18:26:50 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K253951

Device Name
Holmium Laser Therapeutic Apparatus (HZ-A);
Holmium Laser Therapeutic Apparatus (HZ-B);
Holmium Laser Therapeutic Apparatus (HZ-E)

Indications for Use *(Describe)*
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 in use in medical specialties including: Urology,Urinary Lithotripsy, Gastroenterology,ENT, Gynecology 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

## 1 Submitter / Contact Information

| Field | Information |
|---|---|
| **510 (K) #** | K253951 |
| **Date Preparation** | February 27, 2026 |
| **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 |

## 2 Device Information

| Field | Information |
|---|---|
| **Device Trade Name** | Holmium Laser Therapeutic Apparatus |
| **Models** | HZ-A, HZ-B, HZ-E |
| **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 |

## 4 Device Description

The HZ 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 diode-pumped Ho:YAG laser medium, and the laser energy is transmitted to the target site via SMA-905 compatible optical fibers. All models in the series share the same fundamental design and operational principles, differing in maximum average power output, Energy per pulse and frequency.

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

## 5 Intended Use/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 in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology,ENT, Gynecology and general surgery.

## 6 Comparison of Technological Characteristics

| | Subject device | Predicate device | Basis for SE |
|---|---|---|---|
| 510 (k) | / | K201455 | / |
| Model name | Holmium Laser Therapeutic Apparatus | Litho 150, Cyber Ho 150 | / |
| Manufacturer | Potent Medical | Quanta System Spa | / |
| Regulation Number | 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 | Same |
| Regulation Class | Class II | Class II | Same |

| | Subject device | Predicate device | Basis for SE |
|---|---|---|---|
| Product Code | GEX | GEX | Same |
| Device Panel | General & Plastic Surgery | General & Plastic Surgery | Same |
| 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 in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology,ENT, Gynecology and general surgery. | Full indications for use: See Appendix A. | Substantially Equivalent |
| Laser Source | Pulsed Holmium laser (CHT:YAG) | Pulsed Holmium laser (CHT:YAG) | Same |
| Wavelength (nm) | 2,100 nm | 2,100 nm | Same |
| Emission | Pulsed | Pulsed | Same |
| Pulse duration | 90-1000 μs | Up to 1100 μs | Substantially Equivalent |
| Energy per pulse | HZ-A ( up to 4.5 J)<br>HZ-E ( up to 4.5 J)<br>HZ-B ( up to 5.0 J) | up to 5.0 Joule | Substantially Equivalent |
| Frequency | HZ-A ( up to 40 Hz)<br>HZ-E ( up to 40Hz)<br>HZ-B ( up to 60 Hz) | up to 100 Hz | Substantially Equivalent |
| Max average power | HZ-A ( up to 80W)<br>HZ-E ( up to 70W)<br>HZ-B ( up to 90W) | 152W | Substantially Equivalent |
| Delivery system | optical fibers | optical fibers | Substantially Equivalent |
| Aiming beam | Green diode laser < 3 mW | Green diode laser < 5 mW | Substantially Equivalent |

**Conclusion:**

The HZ Series Holmium Laser Therapeutic Apparatus is a similar device to the identified predicate device, sharing the same intended use and fundamental technological principles. Differences in parameters such as pulse duration, energy, frequency, and aiming beam wavelength do not raise new questions of safety or effectiveness. The HZ Series is considered to be substantially equivalent to the identified predicate device.

## 7 Non-Clinical Performance Data

The HZ 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.**

## 8 Substantial Equivalence Conclusion

The HZ Series Holmium Laser Therapeutic Apparatus 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.

Appedix A: Indications for Use (Predicate device)

The Multicavity Holmium 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, Gynaecology, ENT and General Surgery.

Urology

Open and endoscopic surgery (incision, excision, resection, ablation,

vaporization, coagulation and haemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors,
- Ablation of Benign Prostatic Hypertrophy (BPH),
- Transurethral incision of the prostate (TUIP)
- Holmium Laser Resection of the Prostrate (HoLRP)
- Holmium Laser Enucleation of the Prostate (HoLEP)
- Holmium laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy

- Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate
- dehydrate stones.
- Endoscopic fragmentation of kidney calculi
- Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

Gastroenterology

Open and endoscopic Gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitas
- Haemorrhoids
- Cholecy stectomy
- Benign and Malignant Neoplasm

• Angiody splasia
• Colorectal cancer
• Telangiectasias
• Telangiectasias of the Osler-Weber-Renu disease
• Vascular Malformation
• Gastritis
• Esophagitis
• Esophageal ulcers
• Varices
• Colitis
• Mallory-Weiss tear
• Gastric Erosions

Arthroscopy

Arthroscopy/Orthopaedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints ofthe body, excluding the spine but including:

• Ligament and tendon Release
• Contouring and sculpting of articular surfaces
• Capsulectomy in the Knee
• Chondreplasty in the Knee
• Debridement of inflamed synovial tissue
• Chondromalacia Ablation
• Chondromalacia and tears
• Plica Removal
• Meniscectomy
• Loose Body Debridement
• Lateral retinecular release

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including

• Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-SI lumbar discs, including Foraminoplasty Percutaneous Cervical Disc Decompression/Discectomy
  Percutaneous Thoracic Disc Decompression/Discectomy

Gynaecology

Open and laparoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) of soft tissue.

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and

haemostasis of soft tissue and cartilage) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery

General Surgery

Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:

- Appendectomy
- Skin incision
- Excision of external and internal lesions
- Complete of partial resection of internal organs, tumors and lesions
- Biopsy