August 18, 2023

Allengers Global Healthcare Private Limited
Harpreet Singh
Director-Technical
Room No.5, Khasra no. 79, Bhankarpur, Mubarakpur Road
Derabassi, District- Mohali, Punjab 140507
India

Re: K231718
Trade/Device Name: Holmium Medical Laser
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: May 5, 2023
Received: June 13, 2023

Dear Harpreet Singh:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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: 2023.08.18 15:22:10 -04'00'

Tanisha Hithe, MS, MHS
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)*
K231718

Device Name
Holmium Medical Laser

Indications for Use *(Describe)*
The Holmium Medical Laser 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, Gynecology, ENT, Pulmonary Surgery 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
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- 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 of the 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, excisio n, 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

Pulmonary Surgery
Open and endoscopic pulmonary surgery (cutting, vaporization, incision, excision and coagulation of soft tissue)

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 or partial resection of internal organs, tumors and lesions
• Biopsy

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 5

510(k) Summary
K231718

510(k) SUMMARY

(K231718)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92

Applicant /Manufacturer Name and Address	**Allengers Global Healthcare Private Limited** Room No.5, Khasra no. 79, Bhankarpur, Mubarakpur Road, Derabassi, District- Mohali, 140507, Punjab (India) +911762-272600
510(K) Contact person	**Harpreet Singh** **Address:** Room No.5, Khasra no. 79, Bhankarpur, Mubarakpur Road, Derabassi, District- Mohali, 140507, Punjab (India) **Contact Number:** +919876615337 **Email ID:** harpreet.singh@allengers.net
Date Prepared	5th May, 2023
Device/Trade Name	Holmium Medical Laser
Models Names	BLAZE-prime, BLAZE
Regulation Class	Class II
Regulation Name	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation Number	21 CFR 878.4810
Product Code	GEX
Panel	General and Plastic Surgery
Predicate Devices	Cyber Ho 100 (K192600)-Quanta system spa
Reference Devices	Empower H65(K180423), Litho(K163009)- Quanta system spa Lumenis Pulse 120H (K170121)-Lumenis Ltd.

Device Description

The devices belonging to Holmium laser family are laser devices based on a Holmium laser source. The main parts (subsystems) of the device are the Holmium laser source, the power electronics, the optical delivery system, the control electronics and the cooling system. Specific software controls the device functions and allows the user selections. Laser emission is triggered by a footswitch.

Summary of Technical Characteristic

Feature	Subject Device		Predicate Device	Justification for differences
Manufacturer	**Allengers Global Healthcare Pvt. Ltd.**		**Quanta System SPA**	
Models	BLAZE-prime (100W,65W)	BLAZE (35W)	Cyber Ho 100	
510(k)	K231718		K192600	
Manufacturer	Allengers Global Healthcare Pvt. Ltd.		Quanta System SPA	
Device/Trade Name	Holmium Medical Laser		Cyber Ho 100	
Laser Medium	Pulsed Holmium laser (CTH:YAG)		Pulsed Holmium laser (CTH:YAG)	Same
Wavelength	2100nm		2100nm	Same
Emission	Pulsed		Pulsed	Same
Pulse Duration	95- 1500µs		50 - 1100 µs	Similar
Pulse Frequency	3-80HZ (100W) 3-60HZ (65W)	3-30HZ	3-80 Hz	Same
Pulse Energy	0.1J to 5J		Upto 5J	Same
Maximum Average Power	Up to 100 W (100W) Up to 65 W (65W)	Up to 35 W	Up to 105W	Similar
Delivery System	Optical Fiber		Optical Fiber	Same
Aiming Beam				
Type	DPSS		DPSS	Same
Power	Power <5mW		Power <5mW	Same
Wavelength	Wavelength 532nm		Wavelength 532nm	Same
Laser Class	Class 3R		Class 3R	Same

Intended Use/ Indications for Use:

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- Skin incision
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- Biopsy

Accessories

The device is intended to be used together with delivery optical fiber that separately received a FDA clearance for an intended use.

Performance Testing

The Subject device performs testing in accordance with the following recognized consensus standards

- Risk analysis activities, in compliance with the requirements of ISO 14971: 2019 Medical devices - Application of Risk Management to Medical Devices.
- Electrical and laser safety and electromagnetic compatibility tests, in compliance with:
  - IEC 60601-1:2005+ CORR.1:2006+CORR. 2:2007 +AM1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
  - IEC 60601-1-2:2014, 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: 2007+A1:2012 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.
- Software verification and validations, in compliance with FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (issue on 2005). The tests verified that the subject Holmium Medical Laser performs according to its specifications.

Comparison with predicate device

The subject device technological characteristics and indication for use are same to the predicate device and its output power ranges are similar to those of the predicate devices. Other difference between the subject device and predicate device is not raise new types of question regarding the subject device's safety and efficacy.

Conclusion

The Holmium Medical Laser do not introduces any new indications for use, nor does the use of the systems result in any new potential hazard. The Holmium Medical Laser, the subject device is substantially equivalent to the predicate and reference device Cyber Ho100 (K192600), Empower65 (K180423), Litho (K163009), Lumenis pulse120H (K170121).

The intended use, the design principle and the applicable standards for the subject device are identical to those of the predicate and reference device. Some characteristics, for example, their appearance, user interface and the physical dimension are different. However performance test result demonstrates that these differences do not raise any new question of safety and effectives. Therefore, it is Allengers Global Healthcare Pvt. Ltd. option that the subject device appears to be as safe and effective as the predicate and reference device.