August 26, 2025

Heager Gmbh
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K250261
Trade/Device Name: Heager Medical Laser Family (Sabrina/Adolf)
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: August 14, 2025
Received: August 14, 2025

Dear Boyle Wang:

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.08.26 09:38:59 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250261

Device Name

Heager Medical Laser Family (Sabrina/Adolf)

Indications for Use *(Describe)*

The Heager Medical Laser Family device is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

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.

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510(k) Summary

K250261

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

1.0 Submitter's information

Name: Heager Gmbh
Address: Friedrich-Ebert-Straße 111 - 117, 42781 Haan, Germany
Phone Number: +49 21293743770
Contact: Wolfgang Christiani
Email: heagergmbh@gmail.com
Date of Preparation: Jan.23, 2025

Prior submissions

This is the first submission, there is no prior submission.

Designated Submission Correspondent

Mr. Boyle Wang
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Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Heager Medical Laser Family
Common name: Powered Laser Surgical Instrument
Regulation name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Model(s): Sabrina/Adolf.

3.0 Classification

Production code: GEX
Regulation number: 21 CFR 878.4810
Classification: Class II
Panel: General & Plastic Surgery

4.0 Predicate device information

Predicate device
510(k) Number: K212734
Product Name: Diode laser therapy device
Manufacturer: Triangel Rsd Limited

Reference device 1:
510(k) Number: K240179
Product Name: Medical Diode Laser (Model: L2)
Manufacturer: Wuhan Pioon Technology Co., Ltd.

Reference device 2:
510(k) Number: K082721
Product Name: LaserPro 810, LaserPro 980
Manufacturer: PhotoMedex, Inc.

5.0 Indication for Use Statement

The Heager Medical Laser Family is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

6.0 Device description

The Heager Medical Laser Family generates a 980nm wavelength laser to act on a target tissue to achieve hemostasis, ablation, and coagulation of the target tissue.

The Heager Medical Laser Family generates a 1470 nm wavelength laser that acts on the water molecules of the target tissue to achieve the function of treatment of reflux of the saphenous veins associated with varicose veins and varicosities.
The Heager Medical Laser Family has following characteristics:

- Dual wavelengths
- Temperature monitoring system

7.0 Non-Clinical Test Conclusion

Table 1 - Product Technical Specification

Laser type	GaAlAs diode laser

Device model	Sabrina/Adolf
Wavelength	980nm±20nm, 1470nm±20nm
Laser output power	980±20nm cw 20W 1470nm±20nm cw 15W
Security level	Class IV type B
Laser output mode	Continuous, Pulse, Single.
Pulse width	0.1s-10s (stepping 0.1s)
Cooling	Air Cooling
Size	34.5×26.5×27.5cm
Net weight	7.1KG
Fuse	F15AL250V
Aiming beam	Diode laser of 650nm, power Max. 10mW, adjustable brightness.
Beam divergence	314 mrad to 443 mrad
Application systems	Fiber core diameter: 600μm NA>0.22 With SMA905 connector Before use must be steriled
Transmission system	Contact: fibers of 600μm with SMA905 connector; Non-contact: fibers and tips
Operation interface	Color LCD touch screen
Power supply	100-220VAC, 50/60Hz,170VA
Waterproof level	IPX1
Footswitch Waterproof level	IPX8
Transportation & Storage environmental conditions	Temperature:-20°C~70°C, Relative humidity: 10%~90%, Atmospheric pressure: 80KPa~106KPa Without sensible vibration and shock
Application environmental conditions	Temperature:10°C~33°C, Relative humidity: 10%~90%, Atmospheric pressure: 80KPa~106KPa

The Heager Medical Laser Family passed the following IEC test requirements:

1. IEC 60601-1: Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
2. IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances –Requirements and tests.
3. IEC 60601-2-22 Edition 4.0 2019-11 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment.
4. IEC 60825-1 Edition 2.0 2007-03 Safety of laser products - Part 1: Equipment classification and requirements [Including: Technical Corrigendum 1 (2008) Interpretation Sheet 1 (2007) Interpretation Sheet 2 (2007)]
5. IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral

8.0 Clinical Test Conclusion

No clinical study implemented for the Diode laser therapy device.

9.0 Technological Characteristic Comparison Table

Table 2 - General Comparison

Item	Proposed device	Predicated device	Reference device 1	Reference device 2	Remark
Product Code	GEX	GEX	GEX	GEX	Identical
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Class	II	II	II	II	Identical
Product name	Heager Medical Laser Family	Diode laser therapy device	Medical Diode Laser	LaserPro 810, LaserPro 980	-
510(k) No.	K250261	K212734	K240179	K082721	-
Models	Sabrina/Adolf	ST-AR	L2	-	-
Indications for Use	The Heager Medical Laser Family device is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures,	The Diode laser therapy device is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures,	The Medical Diode Laser (Model: L2) is indicated for: -Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue -Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux	The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic(dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN),	Same

	gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.		neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, and thoracic surgery; and Laser Assisted Lipolysis (980 nm only). The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: orthopedics.	
Patient Population	Adult	Adult	Adult	Adult	Same

Table 3 - Performance Comparison

Item	**Proposed Device**	**Predicate Device**	**Reference device 1**	**Reference device 2**	**Remark**
	Heager Medical Laser Family	Diode laser therapy device	Medical Diode Laser	LaserPro 810, LaserPro 980	
	N/A	K212734	K240179	K082721	
Wavelength	980nm±20nm, 1470nm±20nm	980nm±5nm, 1470nm±10nm	1470 nm	980 nm	* Gap 1

Output Power max.	20W/980nm±20nm, 15W/1470nm±20nm	16W/980nm±20%, 4.5W/1470nm±20%	Up to 20W	1-25W/980nm	* Gap 2
Aiming beam	Diode laser of 650nm, power Max. 10mW, adjustable brightness.	650 nm, red 0.5 mW, user controlled intensity	Undisclosed data	635-650nm, adjustable intensity	* Gap 3
Treatment mode	Continuous or Pulsed	Continuous, Pulsed, or Single	Continuous or Pulsed	Continuous or Pulsed	Same
Power supply	100-220VAC, 50/60Hz,170VA	AC110V±11V, 60HZ	110/220 V	100-240 VAC, 540VA max, 50/60Hz	* Gap 4
Interval	980nm 1% ~ 100%, 1470nm 2% ~100%, continuously adjustable energy	980nm 1% ~ 100%, 1470nm 2% ~100%, continuously adjustable energy	1470nm 2% ~100%, continuously adjustable energy	980nm 1% ~ 100%, continuously adjustable energy	Same
Cooling system	Air cooled	Air cooled	Air cooled	Air cooled	Same
Pulse duration range	0.1 - 10 s	0.05 ms - 1 s	10 ms - 10 s	0.05 s - 10 s	* Gap 5

* Gap analysis:

Gap 1: Both of the proposed device and predicate device have 980nm and 1470 nm wavelength. The deviations of wavelength are similar, which does not create additional risk to the product use.

Gap 2: The 980nm max power of the proposed device is close to the predicate device, which does not create additional risk to the product use. For 1470nm max power of the proposed device is the same with reference devices, which does not create additional risks.

Gap 3: The aiming beam of the devices are close, which difference does not create additional risks to the product clinical use.

Gap 4: The power supply range of the proposed device is included in the predicate device and reference devices.

Gap 5: The pulse duration range for subject device K250261 is 0.1 - 10 seconds, while the range for predicate device K212734 is 0.05

milliseconds - 1 second.
For the difference of pulse duration range, we’ ve decided to introduce reference devices, K240179 and K082721 .
The pulse duration range for reference device K240179 is 10 ms - 10 s @1470nm.
The pulse duration range for reference device K082721 is 0.05 s - 10 s @980nm.
Both of the reference devices can comprehensively cover the pulse duration range for subject device K250261.
Therefore, this difference will not affect the safety and effectiveness.

Table 4 - Safety Comparison

Item	Proposed Device	Predicate Device	Reference device 1	Reference device 2	Remark
	Heager Medical Laser Family	Diode laser therapy device	Medical Diode Laser	LaserPro 810, LaserPro 980	
	Pending	K212734	K240179	K082721	
Materials contacting user	N/A Even though Fiber is not a component of “Sabrina/Adolf”, a suitable fiber is necessary to be connected with “Sabrina/Adolf” to transfer laser energy to the patient. The suitable fiber must meet the following requirements. • 510(k) clearance • Fiber core diameter	Fiber	Fiber	Fiber	/

	600μm • NA =0.2 • With SMA905 connector • Meet the requirements of ISO 10993 series standards • Single used • Sterile				
Electric safety	Comply with IEC 60601-1:2005+A1:2012+A2:2020, IEC 60825-1:2014, IEC 60601-2-22:2019	Comply with IEC 60601-1:2005+A1:2012, IEC 60825-1:2014, IEC 60601-2-22:2007+A1:2012	Comply with IEC 60601-1:2005+AMD1:2012 +AMD2:2020 IEC 60825-1:2014 • IEC 60601-2-22:2019	Comply with IEC 60601-1, IEC 60825-1, IEC 60601-2-22	Same
EMC	Comply with IEC 60601-1-2:2014+A1:2021	Comply with IEC 60601-1-2:2014	IEC 60601-1-2:2014+A1:2020	Comply with IEC 60601-1-2	Same

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Heager Medical Laser Family device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K212734.