November 20, 2025

CLASSYS Inc.
Judy Cho
Regulatory Affairs Team Associate, CLASSYS Inc.
208, Teheran-ro, Gangnam-gu
Seoul, 06220
Republic Of Korea

Re: K253123
Trade/Device Name: CuRAS hybrid
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 15, 2025
Received: September 25, 2025

Dear Judy Cho:

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: 2025.11.20 15:00:16 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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.	K253123

Please provide the device trade name(s).

CuRAS hybrid

Please provide your Indications for Use below.

The CuRAS hybrid Nd:YAG laser system indicated for: the incision,excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):
- Tattoo removal: light ink (red, tan, purple, orange, skyblue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Treatment of Lentigines
- Treatment of Cafe-Au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyper-Pigmentation
- Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:
- Tattoo removal: dark ink (black, blue and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation.
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkle

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K253123

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

1. Submitter's Information

- Name: CLASSYS Inc.
- Address: 208 Teheran-ro, Gangnam-gu, Seoul, Republic of Korea
- Postal Code: 06220
- General Telephone: +82-2-1544-3481

Contact Person:

- Contact Person: Ms. Judy Seung-yeon Cho (RA Team Associate, Classys)
- Tel: +82-10-3351-1414
- Email: h.lim@classys.com

2. Date of the summary prepared: Nov 18, 2025

3. Subject Device Information

- 510(k) Number: K253123
- Trade Name: CuRAS hybrid
- Classification Name: Powered Laser Surgical Instrument
- Common Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
- Review Panel: General & Plastic Surgery
- Product Code: GEX
- Regulation: 21 CFR 878.4810
- Regulatory Class: Class II

4. Predicate Device Information

- 510(k) Number: K173038
- Trade/Device Name: CuRAS Nd:YAG Laser
- Regulation Number: 21 CFR 878.4810
- Regulation Name: Powered Laser Surgical Instrument
- Regulatory Class: Class II
- Product Code: GEX
- Manufacturer: Classys, Inc.

5. Reference Device Information

- 510(k) Number: K193266
- Trade/Device Name: Miin
- Regulation Number: 21 CFR 878.4810
- Regulation Name: Powered Laser Surgical Instrument
- Regulatory Class: Class II
- Product Code: GEX
- Manufacturer: LTRA Global Co., Ltd.

6. Reference Device Information

- 510(k) Number: K113588
- Trade/Device Name: SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpieces
- Regulation Number: 21 CFR 878.4810
- Regulation Name: Powered Laser Surgical Instrument
- Regulatory Class: Class II
- Product Code: GEX
- Manufacturer: Lutronic Corporation

7. Device Description

The CuRAS hybrid is indicated for: the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis, at wavelength of 532 nm and 1064 nm. In addition, optional dye handpieces provide output at wavelength of 585 nm and 650 nm.

The CuRAS hybrid system consists of a main unit, power cable, an articulated arm that transmits the laser energy, interchangeable handpieces, a footswitch, key switch, remote interlock connector, and operator/patient protective eyewear. The laser output is user-controlled via the footswitch.

CuRAS hybrid consists of the following components:

- Main Unit
- Handpieces x2
- Handpieces(Optional) x3
- Articulated Arm
- Accessories: Power Cable, Footswitch, Key Switch, Goggles for Operator and Patients, Remote Interlock Connector

8. Indications for Use

The CuRAS hybrid is indicated for: the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):

- Tattoo removal: light ink (red, tan, purple, orange, skyblue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Treatment of Lentigines
- Treatment of Cafe-Au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyper-Pigmentation
- Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:

- Tattoo removal: dark ink (black, blue and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation.
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkle

9. Comparison of Predicate Device

The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Table 9-1: Technical Comparison of the Q-switched Laser

Comparison Item	Proposed Device, CuRAS hybrid, K253123	Predicate Device, CuRAS, K173038	Reference Device, Miin, K193266	Reference Device, SPECTRA, K113588	Assessment of Substantial Equivalence
510(k) Number	K253123	K173038	K193266	K113588	N/A
Trade/Device Name	CuRAS hybrid	CuRAS Nd:YAG Laser	Miin	SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpieces	N/A
Product Code & Regulation Number	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810	Identical
Regulatory Class	Class II	Class II	Class II	Class II	Identical
Manufacturer	CLASSYS Inc.	CLASSYS Inc.	LTRA Global Co., Ltd.	Lutronic Corporation	N/A
Laser Medium	Nd:YAG	Nd:YAG	Nd:YAG	Nd:YAG	Identical
Laser Wavelength	1064nm/532nm/585nm/650nm	1064nm/532nm	1064nm/532nm	1064nm/532nm/585nm/650nm	1064nm/532nm is same as for the Predicate device(K173038) and 585nm/650nm is same as for the reference device(K113588).
Operational mode	Q-switched	Q-switched	Q-switched	Q-switched	Identical
Output Energy	Max. 3J @1064nm Max. 0.4J @532nm Max. 0.26J @585nm Max. 0.16J @650nm	Max 1.6J @1064 nm Max 0.4J @532 nm	Max 3.5J @1064nm Max 0. 5J @532nm	Max. 1.5J @1064 mode Max. 0.4J @532 mode Max. 0.25J @585nm Max. 0.15J @650nm	The Max Output Power of the proposed device is the same/similar and covered by the range of the Max Output Power of the predicate and reference devices. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.
Pulse Width	5-30ns	5-20ns	25ns	5-10ns	The Pulse Width of the proposed device is similar to the Pulse Width of the predicate and reference devices. Therefore, this

Comparison Item	Proposed Device, CuRAS hybrid, K253123	Predicate Device, CuRAS, K173038	Reference Device, Miin, K193266	Reference Device, SPECTRA, K113588	Assessment of Substantial Equivalence
					difference does not affect substantially equivalence on safety and effectiveness.
Repetition Rate	1-15Hz	1-15Hz	0-10Hz	1-10Hz	Identical to K173038
Spot Size	2-10mm	2-10mm	1-10mm	1-8mm	Identical to K173038
Aiming beam	Diode 635nm 5mW	Diode 635nm 5mW	Unknown	655nm	Identical to K173038
User Interface	LCD touch screen	LCD touch screen	LCD touch screen	LCD touch screen	Identical
Optical guide	Articulated arm	Articulated arm	Articulated Arm	Articulated arm	Identical
Electrical Requirements	220-230VAC, 50-60 Hz	220-230VAC, 50-60 Hz	AC 110-230V, 50/60Hz	AC100-120V or AC220-230V, 50/60Hz,	Identical to K173038
Indications for Use	The CuRAS hybrid Nd;YAG las er system in indicated for : the in cision, excision, ablation, vapori zation of soft tissues for general dermatology, dermatologic and g eneral surgical procedures for co agulation and hemostasis. **532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):** - Tattoo removal: light ink (red, tan, purple, orange, skyblue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Treatment of Lentigines - Treatment of Cafe-Au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyper-Pigmentation	The CuRAS Nd;YAG laser system in indicated for : the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. **532nm Wavelength:** - Tattoo removal: light ink (red, tan, purple, orange, skyblue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Treatment of Lentigines - Treatment of Cafe-Au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyper-Pigmentation - Treatment of Becker's Nevi, Freckles and Nevi Spilus **1064nm Wavelength:**	MIIN, Q-Switched Nd: YAG Laser Therapy System (1064nm or 532nm) is indicated for use in incision, excision, ablation, vaporization of soft tissue for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis as follows: **532nm Wavelength** - Tattoo removal (light ink: red, sky blue, green) - Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi - Epidermal Pigmented lesions; including, but not limited to: cafe-au-lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis - Skin Resurfacing for Acne Scars and Wrinkles	The SPECTRA Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. **532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):** -Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) -Removal of Epidermal Pigmented Lesions -Removal of Minor Vascular Lesions including but not limited to telangiectasias -Treatment of Lentigines -Treatment of Cafe-Au-Lait -Treatment of Seborrheic Keratoses -Treatment of Post Inflammatory Hyper	**532nm, 1064nm:** Identical to K173038 and K113588 **585nm, 650nm:** Identical to K113588

Comparison Item	Proposed Device, CuRAS hybrid, K253123	Predicate Device, CuRAS, K173038	Reference Device, Miin, K193266	Reference Device, SPECTRA, K113588	Assessment of Substantial Equivalence
	- Treatment of Becker's Nevi, Freckles and Nevi Spilus **1064nm Wavelength:** - Tattoo removal: dark ink (black, blue and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation. - Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkle	- Tattoo removal: dark ink (black, blue and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation. - Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkle	- Benign cutaneous lesions; including, but not limited to: striae and scars, (excludes the 6S0nm wavelength) - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength) **1064nm wavelength** - Tattoo Removal (dark ink: blue and black) - Dermal Pigmented Lesions; including, but not limited to: Nevus of Ota, Lentigines, Nevi, Melasma and Cafeau-lait - Removal or lightening of hair with or without adjuvant preparation. - Skin Resurfacing for Acne Scars and Wrinkles - Benign cutaneous lesions; including, but not limited to: striae and Scars (excludes the 650nm wavelength) - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)	-Pigmentation-Treatment of Becker's Nevi, Freckles and Nevi Spilus **1064nm Wavelength:** -Tattoo removal: dark ink (black, blue and brown) -Removal of Nevus of Ota -Removal or lightening of unwanted hair with or without adjuvant preparation. -Treatment of Common Nevi -Skin resurfacing procedures for the treatment of acne scars and wrinkle -Treatment of melasma.	

Table 9-2: Technical Comparison of the Pulsed Laser

Comparison Item	Proposed Device, CuRAS hybrid, K253123	Predicate Device, CuRAS, K173038	Reference Device, Miin, K193266	Reference Device, SPECTRA, K113588	Assessment of Substantial Equivalence
510(k) Number	K253123	K173038	K193266	K113588	N/A
Trade/Device Name	CuRAS hybrid	CuRAS Nd:YAG Laser	Miin	SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpieces	N/A
Product Code & Regulation Number	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810	Identical
Regulatory Class	Class II	Class II	Class II	Class II	Identical
Manufacturer	CLASSYS Inc.	CLASSYS Inc.	LTRA Global Co., Ltd.	Lutronic Corporation	N/A
Laser Medium	Nd:YAG	Nd:YAG	Nd:YAG	Nd:YAG	Identical
Laser Wavelength	1064nm	1064nm	1064nm	1064nm	Identical
Operational mode	Pulsed	Pulsed	Pulsed	Pulsed	Identical
Output Energy	Max 3500mJ	Max 1500mJ	Max 3500mJ	Max. 1500mJ	Identical to K193266
Pulse Width	230-350μs	300μs	350μs	Unknown	The Pulse Width of the proposed device is similar to the Pulse Width of the predicate and reference devices and remains within the maximum range demonstrated by the reference device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.
Repetition rate	1-15Hz	1-15Hz	1-15Hz	1-10Hz	Identical to K173038
Spot size	2-10mm	2-10mm	1-8mm	1-8mm	Identical to K173038
Indications for Use	The CuRAS hybrid Nd;YAG laser system in indicated for : the incision, excision,	The CuRAS Nd;YAG laser system in indicated for : the incision, excision,	MIIN, Q-Switched Nd: YAG Laser Therapy System (1064nm	The SPECTRA Laser System is indicated for the incision, excision, ablation,	Identical to K173038

Comparison Item	Proposed Device, CuRAS hybrid, K253123	Predicate Device, CuRAS, K173038	Reference Device, Miin, K193266	Reference Device, SPECTRA, K113588	Assessment of Substantial Equivalence
	ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.	ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.	or 532nm) is indicated for use in incision, excision, ablation, vaporization of soft tissue for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis as follows:	vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.	

10. Summary of Non-Clinical Testing

Verification/validation activities from non-clinical testing as described below demonstrate that the differences do not raise any new issues of safety or effectiveness of the subject device compared to the predicate device.

EMC and Electrical safety of the subject device was tested in compliance with IEC 60601-1 Edition 3.2 (2020); IEC 60601-1-2 Edition 4.1 (2020) and IEC 60601-2-22 Edition 4.0 (2019).

Bench testing such as Laser Output Energy Test, Frequency Test, Spot Size Test, Wavelength Test, Pulse Width Test, and Beam Profile Test were performed to ensure that the subject device performs as intended and meets design specifications.

Biocompatibility testing was performed in compliance with ISO 10993-1 Edition 5 (2018) and FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" to demonstrate biocompatibility of the patient-contacting components of the device.

Software Verification and Validation testing were conducted and documented as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software documentation level for the subject device is considered as ‘Enhanced Documentation’.

11. Summary of Clinical Testing

No clinical study is included in this submission.

12. Conclusion

The CuRAS Hybrid has the same indications for use and incorporates similar design and functional features as the predicate device. Non-clinical testing demonstrates that the CuRAS Hybrid is substantially equivalent to the predicate device, and no new issues of safety or effectiveness are introduced. Therefore, the subject device (K253123) is substantially equivalent to the predicate device (K173038).