



May 21, 2025

Alma Lasers, Inc
Jessica Rivera-Montejo
Director - Regulatory Affairs and Quality Assurance
485 Half Day Rd
Suite 100
Buffalo Grove, Illinois 60089

Re: K251230

Trade/Device Name: The Alma Hybrid Laser System
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, ONG
Dated: March 27, 2025
Received: April 21, 2025

Dear Jessica Rivera-Montejo:

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,

Digitally signed by
TANISHA L. HITHE
-S
L. HITHE -S Date: 2025.05.21
14:56:41 -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
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K251230

Device Name

The Alma Hybrid Laser System

Indications for Use (Describe)

The Alma Hybrid Laser System (Pixel and HyLight CO2 Applicators) is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee). The Alma Hybrid Laser System is cleared for use for the particular indications as follows:

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Laser dermabrasion
- Laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) for the treatment of:

- Wrinkles, rhytids, and furrows (including fines lines and texture irregularities)

Clinical literature demonstrates that skin resurfacing of wrinkles, rhytids, and furrows with CO2 laser increases the amount of sub-epidermal collagen.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- Keratoses, including actinic and seborrheic keratosis, seborrheic vulgaris, seborrheic wart, and verruca seborrhoica;
- Vermilionectomy of the lip;
- Cutaneous horns;
- Solar/actinic elastosis;
- Cheilitis, including actinic cheilitis;
- Lentigines, including lentigo maligna or Hutchinson's malignant freckle;
- Uneven pigmentation/ dyschromia;
- Acne scars;
- Surgical scars;
- Keloids including acne keloidalis nuchae;
- Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum);
- Tattoos;
- Telangiectasia;
- Removal of small skin tumors, including periungual (Koenen) and subungual fibromas;
- Superficial pigmented lesions;
- Aden sebaceous hypertrophy or sebaceous hyperplasia;
- Rhinophyma reduction;
- Cutaneous papilloma (skin tags);
- Milia;
- Debridement of eczematous or infected skin;

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- Basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;
 - Nevi, including spider, epidermal and protruding;
 - Neurofibromas;
 - Laser de-epithelialization;
 - Trichoepitheliomas;
 - Xanthelasma Palpebrarum;
 - Syringoma

Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy.

Vaporization/coagulation of:

- Benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- Lipectomy;
- Verrucae and seborrheic vulgaris, including paronychial, perifungal, and subungual warts.

Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation.

Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation.

Podiatry

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of:

- Verrucae vulgaris/plantar (warts), including paronychial, perifungal, and subungual warts;
- Fungal nail treatment;
- Porokeratoma ablation;
- Ingrown nail treatment;
- Neuromas/fibromas, including Morton's neuroma;
- Debridement of ulcers;
- Other soft tissue lesions.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of:

- Choanal atresia,
- Leukoplakia, including oral, larynx, uvula, palatal, upper lateral pharyngeal tissue;
- Nasal obstruction;
- Adult and juvenile papillomatosis polyps;
- Polypectomy of nose and nasal passages;
- Lymphangioma removal;
- Removal of vocal cord/fold nodules, polyps and cysts;
- Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;
- Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structure and tissue
- Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophageal diverticulectomy (ELAED)];
- Stenosis, including subglottic stenosis; tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil ablation/tonsillotomy;
- Pulmonary bronchial and tracheal lesion removal;

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- Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial);
 - Benign and malignant lesions and fibromas (nose and nasal passages);
 - Benign and malignant tumors and fibromas; (oral);
 - Stapedotomy/stapedectomy;
 - Acoustic neuroma in the ear;
 - Superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease;
 - Telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
 - Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea;
 - Myringotomy/tympanostomy (tympanic membrane fenestration);
 - Uvulopalatoplasty (LAUP, laser UPPP);
 - Turbinectomy and turbinate reduction/ablation);
 - Septal spur ablation/reduction and septoplasty;
 - Partial glossectomy;
 - Tumor resection on oral, subfascial and neck tissues;
 - Rhinophyma;
 - Verrucae vulgaris (warts);
 - Gingivoplasty/gingivectomy.

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:

- Conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosis (BP) lesions;
- Leukoplakia (vulvar dysplasties);
- Incision and drainage (I&D) of Bartholin's and Nabothian cysts;
- Herpes vaporization;
- Urethral caruncle vaporization;
- Cervical dysplasia;
- Benign and malignant tumors;
- Hemangiomas

GYN Laparoscopy

Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of:

- Endometrial lesions, including ablation of endometriosis;
- Excision/lysis of adhesions;
- Salpingostomy
- Oophorectomy/ovariectomy;
- Fimbrioplasty;
- Metroplasty;
- Microsurgery (tubal);
- Uterine myomas and fibroids;
- Ovarian fibromas and follicle cysts;
- Uterosacral ligament ablation;
- Hysterectomy

Neurosurgery

Laser incision, excision, ablation and/or vaporization and of soft tissue in neurosurgery for the

treatment of:

Cranial

- Posterior fossa tumors;
- Peripheral neurectomy;
- Benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas and large tumors);
- Arteriovenous malformation;
- Pituitary gland tumors (transsphenoidal approach).

Spinal Cord

- Incision/excision and vaporization of benign and malignant tumors and cysts;
- Intra- and extradural lesions;
- Laminectomy/ laminotomy/ microdiscectomy.

Orthopedics

Incision/excision and vaporization and of soft tissue in orthopedic surgery. Applications include:

Arthroscopy

- Meniscectomy;
- Chondromalacia;
- Chondroplasty;
- Ligament release (lateral and other);
- Excision of plica;
- Partial synovectomy.

General

- Debridement of traumatic wounds;
- Debridement of decubitus and diabetic ulcers;
- Microsurgery;
- Artificial joint revision;
- PMMA removal.

General/Thoracic Surgery

Incision, excision and vaporization and of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include:

- Debridement of decubitus ulcers, stasis, diabetic and other ulcers;
- Mastectomy;
- Debridement of burns;
- Rectal and anal hemorrhoidectomy;
- Breast biopsy;
- Reduction mammoplasty;
- Cytoreduction for metastatic disease;
- Laparotomy and laparoscopic applications;
- Mediastinal and thoracic lesions and abnormalities;
- Skin tag vaporization;
- Atheroma;
- Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips;
- Pilonidal cyst removal and repair;
- Abscesses;
- Other soft tissue applications.

Dental/Oral Surgery

Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- Gingivectomy- removal of hyperplasia;
- Gingivoplasty;

-
- Incisional and excisional biopsy;
 - Treatment of ulcerous lesions, including aphthous ulcers;
 - Incision of infection when used with antibiotic therapy;
 - Frenectomy (frenum release);
 - Excision and ablation of benign and malignant lesions;
 - Homeostasis;
 - Operculectomy;
 - Crown lengthening;
 - Removal of soft tissue, cysts and tumors;
 - Oral cavity tumors and hemangiomas;
 - Abscesses;
 - Extraction site hemostasis;
 - Salivary gland pathologies;
 - Pre-prosthetic gum preparation;
 - Leukoplakia;
 - Partial glossectomy;
 - Periodontal gum resection.

Genitourinary

Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include:

- Benign and malignant lesions of external genitalia;
- Condyloma;
- Phimosis
- Erythroplasia

ProScan

The Alma Hybrid ProScan CO2 fractional applicator, with wavelength of 10600 nm is indicated for: Laser skin resurfacing (ablation and/or vaporization) of soft tissue.

The Alma Hybrid ProScan 1570nm fractional applicator, with wavelength of 1570 nm, is indicated for: Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue

The Alma Hybrid ProScan CO2 & 1570nm fractional applicator, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.

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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K251230 - Special 510(k) Summary

A summary of Special 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

I. Submitter Information [21 CFR 807.92(a) (1)]

Owner Name	Alma Lasers Inc.
Address	18 Haharash Street NORTH INDUSTRIAL PARK CAESAREA , IL 3079895
Contact Person	Jessica Rivera-Montejo Assoc. Director of Regulatory Email: regulatory@almalasers.com Phone: 224-377-2019 Facsimile: 646-805-1305
Summary Preparation Date	27 March 2025

II. Name of device [21 CFR 807.92 (a) (2)]

Trade or Proprietary Name	The Alma Hybrid Laser System		
Common Device Name(s) and Regulatory Class	Product Code(s)	Classification Panel	Regulation
Electrosurgical cutting and coagulation device and accessories Class II	GEX	General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 878.4810
Powered Laser Surgical Instrument with Microbeam\Fractional Output	ONG	General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 878.4810

III. Predicate Devices [21 CFR 807.92(a) (3)]

Type	510(k) #	Trade Name	Product Code
Primary	K203441	Alma Hybrid	GEX
Reference	K103501	Alma Lasers Pixel CO2 Laser System	GEX

IV. Device Description [21 CFR 807.92(a) (4)]

The Alma Hybrid Laser System consists of:

- Laser system console (containing the optical bench assembly and laser, the microcontroller control electronics and system software, the high voltage power supply, the laser cooling system, the compressed air-purge system, and the service panel)
- LCD control panel with touch-screen technology: the LCD display provides information on the status and settings of The Alma Hybrid Laser System with touch-screen technology provided to input commands into the system.
- Two wavelengths – CO₂ and 1570 nm
- Articulated arm
- Footswitch
- Delivery devices (Pixel applicators, Hylight applicators, Proscan applicator)

V. Intended use of device and Indications for Use [21 CFR 807.92(a) (5)]

Intended Use

The Alma Hybrid Laser System (Pixel and HyLight CO₂ Applicators) is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee). The Alma Hybrid Laser System is cleared for use for the particular indications as follows:

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Laser dermabrasion
- Laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) for the treatment of:

- Wrinkles, rhytids, and furrows (including fine lines and texture irregularities)

Clinical literature demonstrates that skin resurfacing of wrinkles, rhytids, and furrows with CO₂ laser increases the amount of sub-epidermal collagen.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- Keratoses, including actinic and seborrheic keratosis, seborrheic vulgaris, seborrheic wart, and verruca seborrhoica;
- Vermilionectomy of the lip;
- Cutaneous horns;
- Solar/actinic elastosis;
- Cheilitis, including actinic cheilitis;
- Lentigines, including lentigo maligna or Hutchinson's malignant freckle;
- Uneven pigmentation/ dyschromia;

- Acne scars;
- Surgical scars;
- Keloids including acne keloidalis nuchae;
- Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum);
- Tattoos;
- Telangiectasia;
- Removal of small skin tumors, including periungual (Koenen) and subungual fibromas;
- Superficial pigmented lesions;
- Aden sebaceous hypertrophy or sebaceous hyperplasia;
- Rhinophyma reduction;
- Cutaneous papilloma (skin tags);
- Milia;
- Debridement of eczematous or infected skin;
- Basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;
- Nevi, including spider, epidermal and protruding;
- Neurofibromas;
- Laser de-epithelialization;
- Trichoepitheliomas;
- Xanthelasma Palpebrarum;
- Syringoma

Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy.

Vaporization/coagulation of:

- Benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- Lipectomy;
- Verrucae and seborrheic vulgaris, including paronychial, perifungal, and subungual warts.

Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation.

Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation.

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of:

- Verrucae vulgaris/plantar (warts), including paronychial, perifungal, and subungual warts;
- Fungal nail treatment;
- Porokeratoma ablation;
- Ingrown nail treatment;
- Neuromas/fibromas, including Morton's neuroma;
- Debridement of ulcers;
- Other soft tissue lesions.

Laser ablation, vaporization and /or excision in podiatry for complete or partial matrixectomy.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of:

- Choanal atresia,
- Leukoplakia, including oral, larynx, uvula, palatal, upper lateral pharyngeal tissue;
- Nasal obstruction;
- Adult and juvenile papillomatosis polyps;
- Polypectomy of nose and nasal passages;
- Lymphangioma removal;
- Removal of vocal cord/fold nodules, polyps and cysts;
- Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;
- Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structure and tissue
- Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophageal diverticulectomy (ELAED)];
- Stenosis, including subglottic stenosis; tonsillectomy (including tonsillar cryptolysis, neoplasia) and tonsil ablation/tonsillotomy;
- Pulmonary bronchial and tracheal lesion removal;
- Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial);
- Benign and malignant lesions and fibromas (nose and nasal passages);
- Benign and malignant tumors and fibromas; (oral);
- Stapedotomy/stapedectomy;
- Acoustic neuroma in the ear;
- Superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease;
- Telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
- Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea;
- Myringotomy/tympanostomy (tympanic membrane fenestration);
- Uvulopalatoplasty (LAUP, laser UPPP);
- Turbinate reduction and turbinectomy;
- Septal spur ablation/reduction and septoplasty;
- Partial glossectomy;
- Tumor resection on oral, subfascial and neck tissues;
- Rhinophyma;
- Verrucae vulgaris (warts);
- Gingivoplasty/gingivectomy.

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:

- Conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosis (BP) lesions;
- Leukoplakia (vulvar dystrophies);
- Incision and drainage (I&D) of Bartholin's and Nabothian cysts;

- Herpes vaporization;
- Urethral caruncle vaporization;
- Cervical dysplasia;
- Benign and malignant tumors;
- Hemangiomas.

GYN Laparoscopy

Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of:

- Endometrial lesions, including ablation of endometriosis;
- Excision/lysis of adhesions;
- Salpingostomy
- Oophorectomy/ovariectomy;
- Fimbrioplasty;
- Metroplasty;
- Microsurgery (tubal);
- Uterine myomas and fibroids;
- Ovarian fibromas and follicle cysts;
- Uterosacral ligament ablation;
- Hysterectomy.

Neurosurgery

Laser incision, excision, ablation and/or vaporization and of soft tissue in neurosurgery for the treatment of:

Cranial

- Posterior fossa tumors;
- Peripheral neurectomy;
- Benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas and large tumors);
- Arteriovenous malformation;
- Pituitary gland tumors (transsphenoidal approach).

Spinal Cord

- Incision/excision and vaporization of benign and malignant tumors and cysts;
- Intra- and extradural lesions;
- Laminectomy/ laminotomy/ microdiscectomy.

Orthopedics

Incision/excision and vaporization and of soft tissue in orthopedic surgery. Applications include:

Arthroscopy

- Meniscectomy;
- Chondromalacia;
- Chondroplasty;
- Ligament release (lateral and other);
- Excision of plica;
- Partial synovectomy.

General

- Debridement of traumatic wounds;
- Debridement of decubitus and diabetic ulcers;

- Microsurgery;
- Artificial joint revision;
- PMMA removal.

General/Thoracic Surgery

Incision, excision and vaporization and of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include:

- Debridement of decubitus ulcers, stasis, diabetic and other ulcers;
- Mastectomy;
- Debridement of burns;
- Rectal and anal hemorrhoidectomy;
- Breast biopsy;
- Reduction mammoplasty;
- Cytoreduction for metastatic disease;
- Laparotomy and laparoscopic applications;
- Mediastinal and thoracic lesions and abnormalities;
- Skin tag vaporization;
- Atheroma;
- Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips;
- Pilonidal cyst removal and repair;
- Abscesses;
- Other soft tissue applications.

Dental/Oral Surgery

Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- Gingivectomy- removal of hyperplasia;
- Gingivoplasty;
- Incisional and excisional biopsy;
- Treatment of ulcerous lesions, including aphthous ulcers;
- Incision of infection when used with antibiotic therapy;
- Frenectomy (frenum release);
- Excision and ablation of benign and malignant lesions;
- Homeostasis;
- Operculectomy;
- Crown lengthening;
- Removal of soft tissue, cysts and tumors;
- Oral cavity tumors and hemangiomas;
- Abscesses;
- Extraction site hemostasis;
- Salivary gland pathologies;
- Pre-prosthetic gum preparation;
- Leukoplakia;
- Partial glossectomy;
- Periodontal gum resection.

Genitourinary

Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include:

- Benign and malignant lesions of external genitalia;
- Condyloma;

- Phimosis
- Erythroplasia

ProScan

The Alma Hybrid ProScan CO2 fractional applicator, with wavelength of 10600 nm is indicated for: Laser skin resurfacing (ablation and/or vaporization) of soft tissue.

The Alma Hybrid ProScan 1570nm fractional applicator, with wavelength of 1570 nm, is indicated for: Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue

The Alma Hybrid ProScan CO2 &1570nm fractional applicator, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	Hybrid-Hylight Applicator	Hybrid-Hylight Applicator K203441	Alma Pixel CO2 (K103501)	
Wavelength	10600 nm	10600 nm	10600 nm	Same
Pilot beam	650 nm, 3mW	650 nm, 3mW	650 nm, <5 mW	Same
Operation Mode	Repeat pulse/CW	Repeat pulse/CW	Repeat/Super Pulse/CW	Same –
Spot size (mm)	0.15 – 3.1 mm	0.15-3.1 mm	0.125 mm dia spot at tip of spatula at 50 mm working distance 0.2mm dia. Spot at tip of spatula at 100 mm working distance	Same
Repetition Rate	1-5 Hz	1-5 Hz	CW 1-5 Hz	Same
Pulse Duration	10-1000 ms	10-1000 ms	10-1000 ms for CW	Same
Repeat Delay	CW On time: 10 - 1000 msec (0.01 – 1 sec) NA	CW On time: 10 - 1000 msec (0.01 – 1 sec) NA	CW On time: 10 - 1000 msec (0.01 – 1 sec)	Same
Min output energy	5 mJ	5 mJ	1 mJ	Same
Fluence	Max 1746 J/mm2 for 30W system Max 3530 J/mm2 for the 70W system	Max 1746 J/mm2 for 30W system Max 3530 J/mm2 for the 70W system	Max 1746 J/mm2 for 30W system Max 3530 J/mm2 for the 70W system	Same

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
Spot size (mm)	Pixel Applicator- 0.125 to 0.20 mm dia. pixels in a 10 x10 mm ² area (49 pixels) @ 50 mm distance – 0.125 to 0.20 mm dia. pixels in a 11 x 11 mm ² area (81 pixels) @ 100 mm distance	Pixel Applicator- 0.125 to 0.20 mm dia. pixels in a 10 x10 mm ² area (49 pixels) @ 50 mm distance – 0.125 to 0.20 mm dia. pixels in a 11 x 11 mm ² area (81 pixels) @ 100 mm distance	Pixel Applicator- 0.125 to 0.20 mm dia. pixels in a 10 x10 mm ² area (49 pixels) @ 50 mm distance – 0.125 to 0.20 mm dia. pixels in a 11 x 11 mm ² area (81 pixels) @ 100 mm distance	Same
Repetition Rate	0.5-2Hz	0.5-2Hz	1-5 Hz	Same
Pulse Duration	1- 405 ms	1- 405 ms	100-300 ms for pulsed	Same
Min output energy	5 mJ/pixel	5 mJ/pixel	Up to 1000 mJ	Same
Max output energy	SW limited to 150 mJ/pixel	SW limited to 150 mJ/pixel	Up to 1000 mJ SW limited to 150	Same
Output Power	30 W, 70W	30 W, 70W	30 W, 70W	Same
<u>Wavelength</u>	<u>1570nm- For ProScan Applicator</u>	<u>1570nm- For ProScan Applicator</u>	<u>N/A</u>	<u>Same as Primary Predicate</u>
<u>Scan size (mm)</u>	<u>Up to 30mm diameter</u>	<u>Up to 30mm diameter</u>	<u>N/A</u>	<u>Same as Primary Predicate</u>
<u>Output energy</u>	<u>24mJ-144mJ/pixel</u>	<u>24mJ-144mJ/pixel</u>	<u>N/A</u>	<u>Same as Primary Predicate</u>

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
Indications for Use	The Alma Hybrid Laser System (Pixel and HyLight CO2 Applicators) is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee). The Alma Hybrid Laser System is cleared for use for the particular indications as follows: Dermatology & Plastic Surgery The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: • Laser skin resurfacing • Laser dermabrasion	The Alma Hybrid Laser System and Accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery). HyLight-CO2 The Alma Hybrid CO2 non-fractional applicator, with wavelength of 10600 nm is cleared for use for the particular indications as follows: Dermatology & Plastic Surgery The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: * laser skin resurfacing * laser derm-abrasion * laser burn debridement. Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts.	The Alma Pixel CO2 Laser System is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee). The Alma Hybrid Laser System is cleared for use for the particular indications as follows: Dermatology & Plastic Surgery The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: • Laser skin resurfacing	Same as the Reference Predicate

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	- Laser burn debridement. Laser skin resurfacing (ablation and/or vaporization) for the treatment of: - Wrinkles, rhytids, and furrows (including fines lines and texture irregularities) Clinical literature demonstrates that skin resurfacing of wrinkles, rhytids, and furrows with CO2 laser increases the amount of sub-epidermal collagen. Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: - Keratoses, including actinic and seborrheic keratosis, seborrheic vulgaris,	Pixel The Alma Hybrid Pixel CO2 fractional applicator, with wavelength 10600 nm is indicated for: The ablation, vaporization, and coagulation of soft tissue in dermatology and plastic surgery in the performance of skin resurfacing. ProScan The Alma Hybrid ProScan CO2 fractional applicator, with wavelength of 10600 nm is indicated for: - Laser skin resurfacing (ablation and/or vaporization) of soft tissue The Alma Hybrid ProScan 1570nm fractional applicator, with wavelength of 1570 nm, is indicated for: - Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue The Alma Hybrid ProScan CO2 &1570nm fractional applicator, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.	- Laser dermabrasion - Laser burn debridement. Laser skin resurfacing (ablation and/or vaporization) for the treatment of: - Wrinkles, rhytids, and furrows (including fines lines and texture irregularities) Clinical literature demonstrates that skin resurfacing of wrinkles, rhytids, and furrows with CO2 laser increases the amount of sub-epidermal collagen. Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: - Keratoses, including actinic	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	seborrheic wart, and verruca seborrhoica; • Vermilionectomy of the lip; • Cutaneous horns; • Solar/actinic elastosis; • Cheilitis, including actinic cheilitis; • Lentigines, including lentigo maligna or Hutchinson's malignant freckle; • Uneven pigmentation/dyschromia; • Acne scars; • Surgical scars; • Keloids including acne keloidalis nuchae; • Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma)		and seborrheic keratosis, seborrheic vulgaris, seborrheic wart, and verruca seborrhoica; • Vermilionectomy of the lip; • Cutaneous horns; • Solar/actinic elastosis; • Cheilitis, including actinic cheilitis; • Lentigines, including lentigo maligna or Hutchinson's malignant freckle; • Uneven pigmentation/dyschromia; • Acne scars; • Surgical scars; • Keloids including acne	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	pyogenicum/granuloma telangiectaticum); • Tattoos; • Telangiectasia; • Removal of small skin tumors, including periungual (Koenen) and subungual fibromas; • Superficial pigmented lesions; • Aden sebaceous hypertrophy or sebaceous hyperplasia; • Rhinophyma reduction; • Cutaneous papilloma (skin tags); • Milia; • Debridement of eczematous or infected skin; • Basal and squamous cell carcinoma,		keloidalis nuchae; • Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum); • Tattoos; • Telangiectasia; • Removal of small skin tumors, including periungual (Koenen) and subungual fibromas; • Superficial pigmented lesions; • Aden sebaceous hypertrophy or sebaceous hyperplasia;	

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Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions; • Nevi, including spider, epidermal and protruding; • Neurofibromas; • Laser de-epithelialization; • Trichoepitheliomas; • Xanthelasma Palpebrarum; • Syringoma Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy. Vaporization/coagulation of: • Benign/malignant vascular/avascular skin lesions; • Moh's Surgery; • Lipectomy;		• Rhinophyma reduction; • Cutaneous papilloma (skin tags); • Milia; • Debridement of eczematous or infected skin; • Basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions; • Nevi, including spider, epidermal and protruding; • Neurofibromas; • Laser de-epithelialization; • Trichoepitheliomas;	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	Verrucae and seborrheic vulgaris, including paronychial, perifungal, and subungual warts. Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty. Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation. Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty. Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation. Podiatry Laser ablation, vaporization and /or excision of soft tissue for		- Xanthelasma Palpebrarum; - Syringoma Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy. Vaporization/coagulation of: - Benign/malignant vascular/avascular skin lesions; - Moh's Surgery; - Lipectomy; - Verrucae and seborrheic vulgaris, including paronychial, perifungal, and subungual warts. Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty. Laser incision and /or	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	the reduction, removal, and/or treatment of: • Verrucae vulgaris/plantar (warts), including paronychia, perifungal, and subungual warts; • Fungal nail treatment; • Porokeratoma ablation; • Ingrown nail treatment; • Neuromas/fibromas, including Morton's neuroma; • Debridement of ulcers; • Other soft tissue lesions. Laser ablation, vaporization and /or excision in podiatry for complete or partial matrixectomy. Otolaryngology (ENT)		excision of soft tissue for the creation of recipient sites for hair transplantation. Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty. Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation. Podiatry Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of: • Verrucae vulgaris/plantar (warts), including paronychia, perifungal, and subungual warts; • Fungal nail treatment; • Porokeratoma ablation;	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of: • Choanal atresia, • Leukoplakia, including oral, larynx, uvula, palatal, upper lateral pharyngeal tissue; • Nasal obstruction; • Adult and juvenile papillomatosis polyps; • Polypectomy of nose and nasal passages; • Lymphangioma removal; • Removal of vocal cord/fold nodules, polyps and cysts; • Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including		• Ingrown nail treatment; • Neuromas/fibromas, including Morton's neuroma; • Debridement of ulcers; • Other soft tissue lesions. Laser ablation, vaporization and/or excision in podiatry for complete or partial matrixectomy. Otolaryngology (ENT) Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of: • Choanal atresia, • Leukoplakia, including oral, larynx, uvula, palatal, upper lateral	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords; • Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structure and tissue • Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophageal diverticulectomy (ELAED)]; • Stenosis, including subglottic stenosis; tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil		pharyngeal tissue; • Nasal obstruction; • Adult and juvenile papillomatosis polyps; • Polypectomy of nose and nasal passages; • Lymphangioma removal; • Removal of vocal cord/fold nodules, polyps and cysts; • Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	ablation/tonsillotomy; • Pulmonary bronchial and tracheal lesion removal; • Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial); • Benign and malignant lesions and fibromas (nose and nasal passages); • Benign and malignant tumors and fibromas; (oral); • Stapedotomy/stapedectomy; • Acoustic neuroma in the ear; • Superficial lesions of the ear, including		• Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structure and tissue • Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophageal diverticulectomy (ELAED)]; • Stenosis, including subglottic stenosis; tonsillectomy (including tonsillar cryptolysis, neoplasia) and tonsil ablation/tonsillotomy; • Pulmonary bronchial and	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	chondrodermatitis nodularis chronica helices/Winkler's disease; • Telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue); • Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea; • Myringotomy/tympanostomy (tympanic membrane fenestration);		tracheal lesion removal; • Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial); • Benign and malignant lesions and fibromas (nose and nasal passages); • Benign and malignant tumors and fibromas; (oral); • Stapedotomy/stapedectomy; • Acoustic neuroma in the ear; • Superficial lesions of the ear, including chondrodermatitis	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	- Uvulopalatoplasty (LAUP, laser UPPP); - Turbinectomy and turbinate reduction/ablation); - Septal spur ablation/reduction and septoplasty; - Partial glossectomy; - Tumor resection on oral, subfascial and neck tissues; - Rhinophyma; - Verrucae vulgaris (warts); - Gingivoplasty/gingivectomy. Gynecology (GYN) Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of: - Conization of the cervix, including cervical		is nondularis chronica helices/Winkler's disease; - Telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue); - Corpectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea; - Myringotomy/tympanostomy (tympanic membrane fenestration);	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN); • Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosis (BP) lesions; • Leukoplakia (vulvar dystrophies); • Incision and drainage (I&D) of Bartholin's and Nabothian cysts; • Herpes vaporization; • Urethral caruncle vaporization; • Cervical dysplasia;		• Uvulopalatoplasty (LAUP, laser UPPP); • Turbinectomy and turbinate reduction/ablation); • Septal spur ablation/reduction and septoplasty; • Partial glossectomy; • Tumor resection on oral, subfascial and neck tissues; • Rhinophyma; • Verrucae vulgaris (warts); • Gingivoplasty/gingivectomy. Gynecology (GYN) Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	- Benign and malignant tumors; - Hemangiomas. GYN Laparoscopy Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of: - Endometrial lesions, including ablation of endometriosis; - Excision/lysis of adhesions; - Salpingostomy - Oophorectomy/ovariectomy; - Fimbrioplasty; - Metroplasty; - Microsurgery (tubal); - Uterine myomas and fibroids; - Ovarian fibromas and follicle cysts;		- Conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN); - Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosis (BP) lesions; - Leukoplakia (vulvar dystrophies); - Incision and drainage (I&D) of Bartholin's	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	• Uterosacral ligament ablation; • Hysterectomy. Neurosurgery Laser incision, excision, ablation and/or vaporization and of soft tissue in neurosurgery for the treatment of: Cranial • Posterior fossa tumors; • Peripheral neurectomy; • Benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas and large tumors); • Arteriovenous malformation; • Pituitary gland tumors (transsphenoidal approach).		and Nabothian cysts; • Herpes vaporization; • Urethral caruncle vaporization; • Cervical dysplasia; • Benign and malignant tumors; • Hemangiomas. GYN Laparoscopy Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of: • Endometrial lesions, including ablation of endometriosis; • Excision/lysis of adhesions; • Salpingostomy	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	Spinal Cord • Incision/excision and vaporization of benign and malignant tumors and cysts; • Intra- and extradural lesions; • Laminectomy/laminotomy/microdiscectomy. Orthopedics Incision/excision and vaporization and of soft tissue in orthopedic surgery. Applications include: Arthroscopy • Meniscectomy; • Chondromalacia; • Chondroplasty; • Ligament release (lateral and other); • Excision of plica; • Partial synovectomy. General • Debridement of traumatic wounds;		• Oophorectomy/ovariectomy; • Fimbrioplasty; • Metroplasty; • Microsurgery (tubal); • Uterine myomas and fibroids; • Ovarian fibromas and follicle cysts; • Uterosacral ligament ablation; • Hysterectomy. Neurosurgery Laser incision, excision, ablation and/or vaporization and of soft tissue in neurosurgery for the treatment of: Cranial • Posterior fossa tumors; • Peripheral neurectomy; • Benign and malignant tumors and cysts (e.g. gliomas,	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	- Debridement of decubitus and diabetic ulcers; - Microsurgery; - Artificial joint revision; - PMMA removal. General/Thoracic Surgery Incision, excision and vaporization and of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include: - Debridement of decubitus ulcers, stasis, diabetic and other ulcers; - Mastectomy; - Debridement of burns; - Rectal and anal hemorrhoidectomy; - Breast biopsy; - Reduction mammoplasty;		meningiomas (including basal tumors), acoustic neuromas, lipomas and large tumors); - Arteriovenous malformation; - Pituitary gland tumors (transsphenoidal approach). Spinal Cord - Incision/excision and vaporization of benign and malignant tumors and cysts; - Intra- and extradural lesions; - Laminectomy/laminotomy/microdissection. Orthopedics Incision/excision and	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	• Cytoreduction for metastatic disease; • Laparotomy and laparoscopic applications; • Mediastinal and thoracic lesions and abnormalities; • Skin tag vaporization; • Atheroma; • Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips; • Pilonidal cyst removal and repair; • Abscesses; • Other soft tissue applications. Dental/Oral Surgery Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:		vaporization and of soft tissue in orthopedic surgery. Applications include: Arthroscopy • Meniscectomy; • Chondromalacia • ; • Chondroplasty; • Ligament release (lateral and other); • Excision of plica; • Partial synovectomy. General • Debridement of traumatic wounds; • Debridement of decubitus and diabetic ulcers; • Microsurgery; • Artificial joint revision; • PMMA removal. General/Thoracic Surgery	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	• Gingivectomy-removal of hyperplasia; • Gingivoplasty; • Incisional and excisional biopsy; • Treatment of ulcerous lesions, including aphthous ulcers; • Incision of infection when used with antibiotic therapy; • Frenectomy (frenum release); • Excision and ablation of benign and malignant lesions; • Homeostasis; • Operculectomy; • Crown lengthening; • Removal of soft tissue, cysts and tumors; • Oral cavity tumors and hemangiomas; • Abscesses;		Incision, excision and vaporization and of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include: • Debridement of decubitus ulcers, stasis, diabetic and other ulcers; • Mastectomy; • Debridement of burns; • Rectal and anal hemorrhoidectomy; • Breast biopsy; • Reduction mammoplasty; • Cytoreduction for metastatic disease; • Laparotomy and laparoscopic applications; • Mediastinal and thoracic lesions and abnormalities;	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	- Extraction site hemostasis; - Salivary gland pathologies; - Pre-prosthetic gum preparation; - Leukoplakia; - Partial glossectomy; - Periodontal gum resection. Genitourinary Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include: - Benign and malignant lesions of external genitalia; - Condyloma; - Phimosis - Erythroplasia <u>ProScan The Alma Hybrid ProScan CO2 fractional applicator, with wavelength of 10600 nm is indicated for:</u> • Laser		- Skin tag vaporization; - Atheroma; - Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips; - Pilonidal cyst removal and repair; - Abscesses; - Other soft tissue applications. Dental/Oral Surgery Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include: - Gingivectomy-removal of hyperplasia; - Gingivoplasty; - Incisional and excisional biopsy; - Treatment of ulcerous lesions,	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
	<u>skin resurfacing (ablation and/or vaporization) of soft tissue</u> The Alma Hybrid ProScan 1570nm fractional applicator, with wavelength of 1570 nm, is indicated for: • Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue <u>The Alma Hybrid ProScan CO2 &1570nm fractional applicator, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.</u>		including aphthous ulcers; • Incision of infection when used with antibiotic therapy; • Frenectomy (frenum release); • Excision and ablation of benign and malignant lesions; • Homeostasis; • Operculectomy; • Crown lengthening; • Removal of soft tissue, cysts and tumors; • Oral cavity tumors and hemangiomas; • Abscesses; • Extraction site hemostasis; • Salivary gland pathologies;	

Special 510(k) Summary

Parameter	Subject Device	Primary Predicate	Reference Predicate	Similarities / Differences
			• Pre-prosthetic gum preparation; • Leukoplakia; • Partial glossectomy; • Periodontal gum resection. Genitourinary Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include: • Benign and malignant lesions of external genitalia; • Condyloma; • Phimosis • Erythroplasia	

VI. Summary of technological characteristics of the device compared to the predicates [21 CFR 807.92(a)(6)]

The technical characteristics for the Alma Hybrid Laser System are substantially equivalent to the K203441 and K103501 devices.

VII. Performance Testing [21 CFR 807.92(b)(1)]- Performed under K230441

IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for safety

IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance – Electromagnetic Compatibility

IEC 60601-2-22 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 Safety of laser products-Part 1: Equipment Classification, requirements and user's guide

ISO 10993-1 Biological evaluation of medical devices -- Part 1

ISO 17665-1 Sterilization of health care products – moist heat

IEC 62304 Medical Device Software

ISO 14971 Risk Analysis

VIII. Clinical Data [21 CFR 807.92(b) (2)]

Based on the similarities in the safety and effectiveness profiles of the subject and the predicate, no human clinical studies were deemed needed to support this submission.

IX. Conclusions Safety and Effectiveness SE [21 CFR 807.92(b) (3)]

The Alma Hybrid Laser System is as safe and effective as the predicate devices. The proposed Alma Hybrid Laser System has the same intended use and indications as the predicate with proposed expanded indications, similar technological characteristics, and the same principles of operation as its predicate devices. Thus, the Alma Hybrid Laser System is substantially equivalent to its predicate.

Summary of Supporting Data:

A risk assessment and supporting documentation demonstrate that the change does not affect the safety and effectiveness of the device. No new testing is required beyond what was included in the previously cleared submission.

Conclusion:

The modified device, incorporating the new indication for use, remains substantially equivalent to the previously cleared version under Original 510(k) K230441