September 24, 2025

Alma Lasers, Inc
Jessica Rivera-Montejo
Director - Regulatory Affairs and Quality Assurance
485 Half Day Rd
Suite100
Buffalo Grove, Illinois 60089

Re: K250071
Trade/Device Name: Alma FemiLift Pixel CO2 Laser System, Delivery Devices and Accessories
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 27, 2025
Received: August 27, 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.09.24 18:15:04 -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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250071

Device Name
Alma FemiLift Pixel CO2 Laser System, Delivery Devices and Accessories

Indications for Use *(Describe)*
The Alma FemiLift Pixel CO2 Laser System and Delivery Device 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), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee).The Alma FemiLift Pixel CO2 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
• 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 telagiectaticum);
• 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, neoplasma) 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 nondularis 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 acuminate, 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
Alma Lasers Inc.'s Alma FemiLift Pixel CO_2 System

Submitter's Name, Address, Telephone Number, and Contact Person

Alma Lasers Inc.
485 Half Day Rd Ste 100
Buffalo Grove, IL 60089

Contact Person: Jessica Rivera-Montejo, Director Regulatory and Quality
Email: jrivera-montejo@almalasers.com

Date Prepared: September 16, 2025

Name of Device

Trade Name: Alma FemiLift Pixel CO_2 System, Delivery Devices and Accessories

510(k) #: K250071

Classification Name: Laser Instrument, Surgical, Powered Classification

Regulation: 21 CFR 878.4810

Product Code: GEX

Predicate Device

Alma Lasers Pixel CO_2 Laser System, Delivery Device and Accessories (K103501)

Device Description

The Alma FemiLift Pixel CO_2 System is a laser system designed to deliver light energy for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissues in various medical specialties. The system consists of the following major components:

- 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)
- Control panel with touch-screen technology
- Articulated arm
- Footswitch
- Delivery device handpieces, including:
    - Focusing handpieces (**FemiLift-Subject Device**, CO_2 Focus 50mm, and CO_2 Focus 100mm)
    - Pixel handpieces (CO_2 Pixel 7x7 and CO_2 Pixel 9x9),
    - Scanning handpiece

The FemiLift Handpiece is a 50mm focusing handpiece that has been added to the existing suite of handpieces previously cleared under K103501. The FemiLift Handpiece is comprised of a reusable handpiece body and a sterile sleeve ("FemiLift Single-Use Sleeve"). The handpiece body connects to the laser system and directs the laser beam for treatment, using a mirror to deflect the laser beam by 90°. The FemiLift Single-Use Sleeve provides a sterile barrier between the handpiece body and the patient.

The Alma FemiLift Pixel CO_2 System can be used with the CO_2 Focus 50mm and 100mm Handpieces, CO_2 Pixel 7x7 and 9x9 Handpieces, and CO_2 Scanner Handpiece for all of the specific uses indicated for the system, and with the FemiLift Handpiece for the gynecology and aesthetic surgery (dermatology and plastic surgery) indications.

Intended Use / Indications for Use

The Alma FemiLift Pixel CO_2 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).

There is no change in indications for use compared to the predicate device, Alma Lasers Pixel CO_2 Laser System (K103501). Therefore, the subject device has the same intended use as the predicate device.

The complete Indications for Use can be found in Appendix A to this 510(k) Summary.

Comparison of Technological Characteristics

The Alma FemiLift Pixel CO_2 System has the same basic design, materials, operating principle as the predicate device (Alma Lasers Pixel CO_2 Laser System). The primary difference between the devices is the addition of the FemiLift Handpiece, which is a modified version of the CO_2 Focus 50mm handpiece originally cleared with the predicate device. The FemiLift Handpiece includes all of the same components as the CO_2 Focus 50mm Handpiece, except the FemiLift model includes a mirror and single-use sterile sleeve and does not include a standoff or plume extractor nozzle, which are unnecessary for use of the FemiLift Handpiece.

The principles of operation for the FemiLift Handpiece and the CO_2 Focus 50mm Handpiece are nearly identical, with the only difference being the angle at which the operator positions the handpiece relative to the target tissue. Due to the deflection of the laser beam by 90° from the FemiLift model's mirror, the operator holds the FemiLift Handpiece parallel to the target tissue, whereas the CO_2 Handpiece (which does not include a mirror) is held perpendicular to the target tissue. However, these different positions do not change the angle at which the laser beam treatment reaches the patient, which is always perpendicular to the target tissue.

Performance Data

Performance testing was performed for the new FemiLift handpiece, which was the primary difference between the subject device and the predicate device. The company assessed the performance of the FemiLift Handpiece through viral barrier testing of the FemiLift Single-Use Sleeve and through comparative testing between the handpiece power output produced by

the FemiLift Handpiece versus the CO_2 Focus 50mm Handpiece. The viral barrier testing demonstrated that the FemiLift Single-Use Sleeve is impermeable to penetration by microorganisms. The comparative testing demonstrated that the handpiece power output is substantially equivalent between the FemiLift Handpiece and the CO_2 Focus 50mm Handpiece.

The following additional testing was performed to support substantial equivalence:

- Biocompatibility testing per ISO 10993-1;
- Sterilization validation testing per ISO 11135;
- Packaging validation testing per ASTM D4332 and ASTM D4196;
- Electrical safety and EMC testing per IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-22; IEC 60825-1; IEC 62304
- Software validation testing.

In all instances, the FemiLift Handpiece functioned as intended and the results met the pre-defined acceptance criteria.

Conclusion

The Alma FemiLift Pixel CO_2 System has the same intended use and indications for use as the predicate device (Alma Lasers Pixel CO_2 Laser System, K103501).

The primary technological difference is the addition of the FemiLift Handpiece, which has similar technological characteristics and principles of operation as the predicate device's CO_2 Focus 50mm Handpiece. Although the FemiLift Handpiece includes a mirror and sterile sleeve whereas the predicate CO_2 Focus 50mm Handpiece does not, these differences do not raise different questions of safety or effectiveness because they do not change the overall intended therapeutic use of the laser system, or affect the fundamental scientific technology used to achieve the device's intended use. Furthermore, performance testing of the technological differences showed that the new FemiLift Handpiece is as safe and effective as the predicate device's CO_2 Focus 50mm Handpiece.

Therefore, the Alma FemiLift Pixel CO_2 System is substantially equivalent to the predicate device (K103501).

Appendix A: Complete Indications for Use Statement

The Alma FemiLift Pixel CO_2 System is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: gynecology and aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee).

The Alma FemiLift Pixel CO_2 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
- 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 CO_2 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 telagiectaticum)
- 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.

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 structures 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
- 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 nondularis 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

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 acuminate, 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 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
- Extractions site hemostasis
- Salivary gland pathologies
- Pre-prosthetic gum preparation
- Leukoplakia
- Partial glossectomy
- Periodontal gum resection

Genitourinary

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

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