

**Attachment 15**  
**510(k) Summary Statement for K963339 the**  
**Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers**

**I. General Information**

**Submitter:** Coherent Medical Group  
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**II. Names**

**Device Names:** Coherent ULTRAPULSE Family of Carbon Dioxide Surgical Lasers and Delivery Accessories.

**Primary Classification Name:** Laser Powered Surgical Instrument (and Accessories).

**III. Predicate Devices**

- Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers and Delivery Accessories (K951812 & K912029) marketed by Coherent Medical Group;
- Coherent Family of Scanner Handpieces for use with Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers (K946304) marketed by Coherent Medical Group;
- Coherent Xanar XA-50 Carbon Dioxide Surgical Laser (K853620) marketed by Coherent/Xanar
- Sharplan Carbon Dioxide SilkLaser with FeatherTouch and SilkTouch (510(k) cleared November 4, 1996 - K number unknown, K960521, & K955621)

**IV. Product Description**

The Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers (and its delivery accessories) are intended to be used to deliver carbon dioxide light energy for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in a variety of medical specialties.

Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers are comprised of the following main components:

- a laser console and tower;
- a counterbalanced articulated arm and delivery system;
- control and display panels;
- footswitch and handswitch delivery controls;
- a remote control unit;
- a filtered air pump purge system; and
- a variety of delivery device accessories (handpieces, scanners, waveguides, micromanipulators, optical couplers and laparoscopic adapters, and insufflation and purge gas systems).

## V. Indications for Use

The Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers and the Delivery Accessories that are used with them to deliver light energy are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology; plastic surgery; podiatry; neurosurgery; gynecology; otorhinolaryngology (ENT); arthroscopy (knee surgery); and open and endoscopic general surgery.

The Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers are safe and effective when indicated for use in specific surgical applications including:

### **Dermatology & Plastic Surgery**

- Ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery (using the CPG UltraScan Handpiece or the TrueSpot family of collimated fixed and variable spot-sized handpieces) in the performance of laser skin resurfacing and laser derm-abrasion (using the CPG UltraScan Handpiece or the TrueSpot family of collimated fixed and variable spot-sized handpieces), and laser burn debridement.
- Laser skin resurfacing (ablation and/or vaporization) in dermatology and plastic surgery using the CPG UltraScan Handpiece or the TrueSpot family of collimated fixed and variable spot-sized handpieces for the treatment of wrinkles, rhytids, and furrows.

Clinical study demonstrated that skin resurfacing of wrinkles, rhytids, and furrows with the ULTRAPULSE CO<sub>2</sub> laser increases the amount of sub-epidermal collagen.

- Laser skin resurfacing (ablation and/or vaporization) of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, solar/actinic elastosis, actinic cheilitis, lentinges, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas), tattoos, telangiectasia, squamous cell carcinoma, epidermal nevi, xanthelasma palpebrarum, syringoma, and verrucae vulgares (warts).

### **Dermatology, Plastic Surgery and General Surgery**

- Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery for the performance of blepharoplasty.

Clinical studies<sup>1, 2, 3, 4, 5, 6</sup> demonstrate that CO<sub>2</sub> laser blepharoplasty provides cosmetic results that are equivalent to cold steel blepharoplasty, is up to 33% faster than cold steel blepharoplasty, provides good hemostasis and visualization of the surgical field, and results in less ecchymosis, edema, and bruising when compared to cold steel.

1. Morrow, D.; Morrow L. *CO<sub>2</sub> Blepharoplasty: A Comparison with Cold-Steel Surgery* J Dermatol Surg Oncol 1992; 18:307-313.
2. David, L. *The Laser Approach to Blepharoplasty* J Dermatol Surg Oncol 1988; 14:741-746.
3. David, L.; Sanders G. *CO<sub>2</sub> Laser Blepharoplasty: A Comparison to Cold Steel and Electrocautery* J Dermatol Surg Oncol 1987; 13:2:110-114.
4. Baker, S.; Muenzler, W.; Small, R.; Leonard, J. *Carbon Dioxide Laser Blepharoplasty* Ophthalmology 1984; 91:238-244.
5. David, L.; Abergel, R. *CO<sub>2</sub> Laser Blepharoplasty Cosmetic Surgery of the Skin: Principles and Techniques*, B.C. Decker, Philadelphia, PA, 1991, Chapter 15:295-300.
6. Glassberg, E.; Babapour, R.; Lask, G. *Current Trends in Laser Blepharoplasty* Dermatol Surg 1995; 21:1060-1063.

## V. Indications for Use - Continued

### **Dermatology, Plastic Surgery and General Surgery - Continued**

- Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery for the creation of recipient sites for hair transplantation.

Clinical studies<sup>7, 8, 9, 10</sup> demonstrate that the use of ULTRAPULSE CO<sub>2</sub> surgical lasers, as compared to cold steel, results in faster operative times, reduced bleeding, no compression of laser created sites (due to removal of scalp tissue vaporized from laser created sites), and greater hair density (due to removal of scalp tissue vaporized from laser created sites).

### **Podiatry**

- Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares (warts)
- Laser ablation, vaporization, and/or excision in podiatry for matrixectomy.

### **Otorhinolaryngology (ENT)**

- Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of choanal atresia, leukoplakia of larynx, nasal obstruction, adult and juvenile papillomatosis polyps, rhinophyma, and verrucae vulgares (warts).

### **Gynecology**

- Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of cervical intraepithelial neoplasia, condyloma acuminata, leukoplakia (vulvar dystrophies), and vulvar and vaginal intraepithelial neoplasia

### **Neurosurgery**

- Laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of basal tumor-meningioma, posterior fossa tumors, peripheral neurectomy, and lipomas/large tumors.

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7. Unger, W. *Laser Hair Transplantation II* Dermatol Surg 1995; 21:759-765.

8. Fitzpatrick, R. *Laser Hair Transplantation - Tissue Effects of Laser Parameters* Dermatol Surg 1995; 21:1042-1046

9. Ho, C.; Nguyen, Q.; Lask, G.; Lowe, N. *Mini-Slit Graft Hair Transplantation Using the Ultrapulse Carbon Dioxide Laser Handpiece* Dermatol Surg 1995; 21:1056-1059.

10. Unger, W.; David, L. *Laser Hair Transplantation J Dermatol Surg Oncol* 1994; 20:515-521.

## **VI. Rationale for Substantial Equivalence**

The Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers and their delivery device accessories share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to the Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers (K951812 & K912029), the Coherent Family of Scanner Handpieces (K946304), the Coherent Xanar XA-50 Carbon Dioxide Surgical Laser (K853620), and to the CO<sub>2</sub> SilkLaser with FeatherTouch and SilkTouch Flash Scanners, marketed by Sharplan Lasers, Inc (510(k) cleared November 4, 1996 - K number unknown, K960521, and K955621). In addition, clinical data demonstrated that the Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers are safe and effective when indicated for use for additional specific applications in a variety of medical specialties.

## **VII. Safety and Effectiveness Information**

Clinical data was provided to demonstrate that the Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers are safe and effective, when indicated for use for specific applications in the medical specialties of dermatology; plastic surgery; podiatry; neurosurgery; gynecology; otorhinolaryngology (ENT); and general surgery.

## **VIII. Conclusion**

The Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers were found to be substantially equivalent to similar currently marketed and predicate surgical laser devices. The Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers share the same indications for use, similar design features, and similar functional features as the currently marketed Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers and delivery devices, and are substantially equivalent to the Coherent Xanar XA-50 and the Sharplan SilkLaser (with FeatherTouch and SilkTouch Flash Scanners).

Clinical study results demonstrated Coherent ULTRAPULSE CO<sub>2</sub> Surgical Lasers are safe and effective for use in a variety of specific indications for use in a variety of medical specialties including dermatology; plastic surgery; podiatry; neurosurgery; gynecology; otorhinolaryngology (ENT); and general surgery.