

K 960521

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**510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. SilkTouch CO2 Flash Scanner Accessory**

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Sharplan Lasers, Inc. SilkTouch CO2 Flash Scanner is based on a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the Robbins Acrotorque & Bell Hand Engines, the Sharplan Model 1120 CO2 Surgical Laser, and the Sharplan Lasers, Inc. SwiftLase CO2 Flash Scanner Accessory (aka SilkTouch).

1. **Sharplan Lasers, Inc.**
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2. **Model:** Sharplan Lasers, Inc. SilkTouch CO2 Flash Scanner Accessory
3. **Predicate Devices:** The Robbins Acrotorque & Bell Hand Engines, the Sharplan Model 1120 CO2 Surgical Laser, and the Sharplan Lasers, Inc. SwiftLase CO2 Flash Scanner Accessory (aka SilkTouch).
4. **Description:** The Sharplan Lasers, Inc. SilkTouch CO2 Flash Scanner Accessory is a motorized, laser beam deflection system that is attached to a CO2 laser articulating arm. The device redirects a focused laser beam through moving mirrors, within a specified pattern scan area. Similar to the common surgeon's technique of manually scanning a focused beam over a treatment area, the constantly moving beam of the SilkTouch Flash Scanner limits the time of laser exposure on tissue while providing sufficient power density for tissue vaporization at low average power levels. The SilkTouch Flash Scanner has controls for varying the scanned area from 0.9 to 9 mm and completes the scan within 0.05 - 0.45 seconds. This device is used with CO2 handpieces or micromanipulators. When the unit is turned off, the connected laser operates to its specifications and allows incision or manual scanning for vaporization purposes.
5. The Sharplan Lasers, Inc. SilkTouch CO2 Flash Scanner Accessory is substantially equivalent to the following devices: The Robbins Acrotorque & Bell Hand Engines, the Sharplan Model 1120 CO2 Surgical Laser, and the Sharplan SwiftLase CO2 Flash Scanner Accessory (aka SilkTouch) (preamended, K936109, K941312, and K936109, respectively). It is indicated for incision/excision, ablation/vaporization, coagulation, and debridement of soft tissue in Plastic Surgery/Dermatology. Plastic Surgery/Dermatology procedures encountered are: laser skin resurfacing/dermabrasion, blepharoplasty, rhinophyma, squamous cell carcinoma, buccal hemangioma, telangiectasis, the treatment of wrinkles or rhytides, and scar revision.

REVISED APRIL 4, 1996

510(k) Summary of Safety and Effectiveness (continued)
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6. From a clinical performance perspective, the aforementioned devices while are not identical, perform the same function for the same indications. Regarding the technological similarities; while two of the predicated devices are of the same photonic technology with minor differences, the non-laser device relies upon a mechanical technology to achieve its therapeutic effect. Based upon the clinical information submitted, Sharplan Lasers, Inc. believes that the expanded indications for this device raises no safety or efficacy concerns.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.

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