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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 Norcross Scientific SurgiScan CO2 Scanner, the A-Z Surgical Super Punch, and the Robbins Hand Engine.

1. Sharplan Lasers, Inc.
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George J. Hattub, Director of Regulatory Affairs
May 6, 1996
1-800-394-2000, ext. 531
2. **Model:** Sharplan Lasers, Inc. SilkTouch CO2 Flash Scanner Accessory
3. **Predicate Devices:** Norcross Scientific SurgiScan CO2 Scanner, the A-Z Surgical Super Punch, the Robbins Acrotorque Hand Engine.
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 setting the exposure time. This device is used with a CO2 handpiece. 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 Norcross Scientific SurgiScan CO2 Scanner, the A-Z Surgical Super Punch, and the Robbins Acrotorque Hand Engine. It is indicated for soft tissue incision of recipient sites for laser assisted hair transplantation.

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6. From a clinical performance perspective, the aforementioned devices while are not identical, perform the same function for the same indication. Regarding the technological similarities; while two of the predicate devices are of the same photonic technology with minor differences, the non-laser devices relies upon a mechanical technology to achieve its clinical effect. Based upon the histological 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.