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SHARPLAN LASERS, INC.

K963229

510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. CO_2 Laser Systems for Laser Assisted Myringotomy/Tympanostomy Indication

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 Sharplan CO_2 Laser Systems for Laser Assisted Myringotomy/ Tympanostomy Indication is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the Sharplan CO_2 Lasers which are intended for use in ENT and the ScalpelTEC, Inc. Myringotomy Safety Scalpel .

1 . Sharplan Lasers, Inc.
1 Pearl Court
Allendale, NJ 07401
George J. Hattub, Director of Regulatory Affairs/Quality Assurance
August 16, 1996

2 . **Model:** Sharplan Models 20c, 30c, and 40c CO_2 Lasers

3 . **Predicate Devices:** The Sharplan CO_2 Lasers which are intended for use in ENT and the ScalpelTEC, Inc. Myringotomy Safety Scalpel.

4 . **Description:** The Sharplan Models 20c, 30c, and 40c CO_2 Lasers are surgical lasers are medical devices which capable of incising soft tissue. They emit a treatment laser beam at a wavelength of 10.6 µm up to 40 watts and a 3 mWatt HeNe aiming beam.

5 . The Sharplan Models 20c, 30c, and 40c (for this indication) are substantially equivalent to the following devices: The Sharplan CO_2 Lasers which are intended for use in ENT and the ScalpelTEC, Inc. Myringotomy Safety Scalpel. They are intended for soft tissue incision in ENT for the specific indication of Myringotomy/Tympanostomy.

Clinical results from 80 patients, which were obtained at 2 sites, were presented as part of this 510(k) submission, along with historical data, in order to demonstrate the safety and effectiveness of the device.

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6. From a design and clinical perspective, the predicate and candidate laser devices, are of the same technology (they are identical), and have the same intended use. The other predicate device, which is a surgical scalpel, has the same intended use as the candidate device. Based upon an analysis of the overall performance characteristics for the devices, Sharplan Lasers, Inc. believes that no significant differences exist. Furthermore, this expanded indication should not raises any concerns regarding the safety or effectiveness of the Sharplan Lasers, Inc. CO_2 Laser Systems for a Laser Assisted Myringotomy/Tympanostomy Indication

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.