

APR 30 1996

K 960040

**510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. Ultra Model 4300 Ultrasonic Aspirator
System for Laparoscopic Use**

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 Model 4300 Ultrasonic Aspirator for use in Laparoscopy is based on a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the Valley Lab CUSA and the Sharplan Ultrasonic Aspirator .

1. Sharplan Lasers, Inc.
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George J. Hattub, Director of Regulatory Affairs
Updated: October, 1995
2. **Model:** Sharplan Ultra Model 4300 Ultrasonic Aspirator system for Laparoscopy
3. **Predicate Devices:** The Valley Lab CUSA Ultrasonic Aspirator for Laparoscopy and the Sharplan Ultrasonic Aspirator .
4. **Description:** The Sharplan Ultra Model 4300 Ultrasonic Aspirator System is a surgical tool which achieves fragmentation and excision of unwanted tissue by high frequency vibration of the titanium tip housed in the handpiece. The application of the vibration tip to the unwanted tissue results in the rupture of the tissue. Irrigation and aspiration of the debris is also accomplished by the system. There accessories to the system are various handpieces, one of which can be used in laparoscopy.
5. The Sharplan Ultra Model 4300 Ultrasonic Aspirator is substantially equivalent to the following devices: The Valley Labs CUSA and the Sharplan Ultrasonic Aspirator (K921251 and K883091, respectively). It is indicated for use in laparoscopic surgical procedures where fragmentation, emulsification, and aspiration of soft is desirable.

510(k) Summary of Safety and Effectiveness (continued)
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System For Use in Laparoscopy

- 6 . From a technological and clinical performance perspective, the aforementioned devices while are not identical, perform the same function and are of the same technology. The modification to the candidate device involved changing the length of the probe so that it will have the ability to utilized in laparoscopic procedures. Based upon a comparison of the performance characteristics of the devices, no significant differences exist. In regards to safety or effectiveness of the Sharplan Ultra Model 4300 Ultrasonic Aspirator System for Laparoscopic Use, Sharplan Lasers, Inc. believes that this modification and expanded indication does not change the performance characteristics of the device and raises no 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.