

SEP 25 1986

K961771

## SUMMARY OF INFORMATION SUPPORTING SAFETY AND EFFECTIVENESS:

The AUTO SUTURE\* Suction / Irrigation\*\* device is identical in safety and effectiveness to its currently marketed predicate - U.S. Surgical Corp.'s Endoscopic Suction / Irrigation\*\* device - 510(k) #K903207. United States Surgical Corporation has been manufacturing hand instruments as accessories in surgical procedures for a number of years. It is now the intention of USSC to expand the utility of the AUTO SUTURE\* Endoscopic Suction / Irrigation\*\* device to allow the surgeon to gently blow blood and debris from the surgical site. The information included in this notification demonstrates that the device is substantially equivalent to its predicate in respect to design, function, performance, labeling and sterilization. *The sole difference between the subject and device and the predicate device, is that the predicate device is indicated for endoscopic surgery while the subject device is only indicated for open and thoracoscopic surgery (non-insufflated).*

- Both the subject and predicate devices are designed and to perform the exact same functions.
- Both the subject devices and other currently marketed United States Surgical Corporation devices are manufactured in the same facilities, using similar processes and controls.
- Both the subject devices and other currently marketed United States Surgical Corporation devices are packaged in the same facilities using similar processes and controls.
- Both the subject and predicate devices perform the exact same function in the same way.
- Both the subject and predicate devices are manufactured from the exact same bio-approved materials

\* Trademark of United States Surgical Corporation

\*\* Trademark name not yet determined