SUMMARY OF SAFETY AND EFFECTIVENESS S-SCORT® MODEL 2500 PORTABLE SUCTION PUMP

MAR - 5 1997

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. 510(k) Submitter, Contact Person and Date Summary Prepared:

Sam Say

Summary Prepared On: December 16, 1996

SSCOR, Inc. 11064 Randall Street Sun Valley, CA 91352 (818) 504-4054

2. Device Name:

Trade/Proprietary Name:

S-SCORT® Model 2500 Portable

Suction Pump

Common/Usual Names:

Powered Portable Aspiration Pump Powered Portable Suction Apparatus

Classification Name: Powered Suction Pump

3. Substantial Equivalence Information:

Predicate devices of the same type which the S-SCORT® Model 2500 Portable Suction Pump is substantially equivalent for purposes of Section 510(k) of the Food, Drug and Cosmetic Act:

SSCOR S-SCORT® Jr. Model 90024B

4. <u>Device Description and Indications</u>:

The S-SCORT® Model 2500 is a portable suction pump to be used by professional personnel for constant suctioning. The unit comes equipped with a pump, regulator, battery, canister, suction tubing, suction tip with vent control, and carrying case. It can be used in hospital crash cart suction; patient transport; surgi-center back-up suction; emergency medical service; and home health care/nursing homes.

5. <u>Comparison of Technological Characteristics with Predicate</u> <u>Devices:</u>

The S-SCORT® Model 2500 is technologically similar in design and operation to the predicate devices with respect to pump, battery, regulator, electrical input & output, airflow, and negative pressure.