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510(k) SUMMARY
for
DSP Worldwide's
Snowden-Pencer Computerized High Flow Insufflator

1. DATE PREPARED

July 9, 1996

2. SPONSOR INFORMATION

Address: DSP Worldwide
600 Airport Road
Fall River, MA 02720-4740

Contact: Timothy N. Thomas
Phone: 508-677-6545
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3. DEVICE NAME

Proprietary Name:	Snowden-Pencer Computerized High Flow Insufflator
Common/Usual Name:	Insufflator
Classification Name:	Laparoscopic Insufflator

4. DEVICE DESCRIPTION AND INTENDED USE

The Snowden-Pencer Computerized High Flow Insufflator is intended to provide intra-abdominal distention during laparoscopic surgery. The device is software controlled and provides numerous features intended to optimize the process of establishing and maintaining pneumoperitoneum during laparoscopic surgery. These features include selection of operating modes, a CO_2 tank volume display, flow control mode selections, selectable flow rates and pressure setting, continual monitoring of the patient's abdominal pressure, automatic venting of excess patient pressure, and a video screen interface for display of insufflation parameters/data.

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5. Comparison To Predicate Devices

The Snowden-Pencer Computerized High Flow Insufflator is similar in design, function, and intended use to other high flow insufflators currently in commercial distribution in the United States. The predecessor Snowden-Pencer Computerized High Flow Insufflator (K920986) had many of the identical features to the current model device with the exception of the continuous monitoring of patient pressure, the CO_2 warmer, and the video interface. These three new features have been added to the device in order to improve device performance and user convenience. Other electronic high flow insufflators, such as the WISAP Flow Therme Insufflator (K952508) also include a CO_2 heater.

6. Device Testing

Performance testing conducted on the Snowden-Pencer Computerized High Flow Insufflator includes software verification and validation, UL 544 testing and certification, VDE 0871/0876/0877 and CISPR 11:1990/EN55011 testing/certification for radiated emissions (EMI/EMC). The device was also tested by the Emergency Care Research Institute (ECRI) and conforms to the ECRI Test Criteria for High-flow Laparoscopic Insufflators.