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K963304

stryker ENDOSCOPY
2590 Walsh Avenue, Santa Clara, CA 95051 (408)567-9100 FAX (408)567-2507

SUMMARY OF SAFETY AND EFFECTIVENESS — 510(K) # K963304

Device Name :

Current Classification Name	:	Arthroscope and accessories CFR 888.1100 Class II
Common and Usual Name	:	Arthroscopy Pump
Propriety Name	:	Stryker Tempest Orthopedic Pump
Device Sponsor	:	Stryker Endoscopy 2590 Walsh Avenue, Santa Clara, CA 95051 FDA Registration # 2936485
Regulatory Classification	:	Class II

This summary of 510(k) safety and effectiveness being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The Stryker Tempest Orthopedic Pump System, consisting of Pump Console which powers disposable Tube Set, and Pressure Sensing Cannula, 510(k) # K944593, during orthopedic surgery is equivalent in intended use, safety and effectiveness to existing Stryker Infusion Pump, 510(k) # K910858, used in similar applications, by Stryker Corporation.

The disposable tube set utilized in Stryker Tempest Orthopedic Pump, will be provided sterile for single applications. The material of constructions, maximum pressure and flow rate are equivalent to currently marketed products. As proven in Orthopedic applications, these design offer the required precision for controlling the joints distension.

The Tempest Orthopedic Pump technology utilized in this device is equivalent to existing marketed products. Power modality, intended use, methods of sterilization and safety risks are substantially equivalent. The Stryker Tempest Orthopedic Pump is electrically powered and is designed to meet CSA Electromedical Standard Number C22.2 Number 125, and UL 544 Standards.

The disposable tube set ETO sterilization processes are validated per AAMI standard ST 27, to a S.A.L. of 10^{-6}. Gamma irradiation validation is per AAMI standard ST 32, method 1, section 5.2.3.1., for sterile packaged, single use disposable tube set. The minimum dose for an S.A.L. of 10^{-6} is 1.66 Mrads. The biocompatibility testing will include USP Intracutaneous, USP Systemic Toxicity Test, Maximization, USP MEM Elution, and Hemolysis. These validation are equivalent to the existing marketed products.

The Tempest Orthopedic Pump is designed with appropriate safety features for over pressure controls and alarm. First, under normal Run/Stop mode, the pump prevents the pressure sensed at the joint or body cavity from exceeding 150 mmHg. The pump motor will stop, a red light emitting diode illuminates, and outflow solenoid valve opens to relieve excess pressure. Under Lavage mode, any pressure above 150 mmHg for 3 seconds will trigger an uninterrupted audible alarm. Second, if the pump will not function if the pressure does not detect a change in actual pressure within four seconds, the pump motor will stop, followed by an audible alarm. The ONLY way to re-activate the pump is to depress the RUN/STOP switch. Third, the Lavage feature has an over pressure alarm. When using Lavage feature, and joint pressure go above 150 mmHg for 3 seconds, the uninterrupted audible alarm will sound.

A reusable hand control will be offered to allow surgeons to perform surgery in the sterile field.

Overall, the Stryker Tempest Orthopedic Pump System does not raise any new safety and efficacy concerns when compared to Infusion pump. Therefore, the Stryker Pump System is substantially equivalent to Stryker Infusion Pump System.

Indications For Use : The Stryker Tempest Orthopedic Pump is intended to be used by surgeons in Orthopedic joints, including the knee, shoulder, ankle, elbow, wrist, and temporomandibular joints. It will be used to distend joints.

The distension and saline circulation allow better viewing of the joint and tissues, as well as, irrigation of loose debris. The Tempest Orthopedic Pump replaces currently used manual infusion systems, utilizing either a bulb syringe or gravity flow. The Stryker Orthopedic Pump is to be used with Stryker Arthroscopes, and Pressure Sensing Cannula, found substantially equivalent under 510(k) number K771200, Arthroscopes, and K944593, Pressure Sensing Cannula, respectively.

1/16/97

Roy S. Chin
Associate Project Engineer