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Device Name:

Current Classification Name	:	Arthroscope and accessories CFR 888.1100 Class II
Expanded Classification Name	:	Surgical instruments motors/accessories CFR 878.4820 Class I
Common and Usual Name	:	Surgical Shaver
Proprietary Name	:	Thermo-Plastic Shaver Blade

Device Sponsor

:	Stryker Endoscopy 2590 Walsh Avenue Santa Clara, CA 95051 FDA Registration No. 2936485
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Regulatory Classification

: Class II

SUMMARY OF SAFETY AND EFFECTIVENESS FOR THERMO-PLASTIC SHAVER BLADES

The Thermo-Plastic Shaver Blade is substantially equivalent to the Linvatec, Merlin Polyblade shaver manufactured by Linvatec per K940515.

The Thermo-Plastic Shaver Blades, consisting of an inner Thermo-Plastic and stainless steel tube which rotates inside of a stainless steel tube through the use of an electrical motor in a handpiece, is equivalent in intended use, safety and effectiveness to existing Thermo-Plastic shaver blades, used in similar applications, by Linvatec.

The disposable Thermo-Plastic Shaver Blades are for orthopedic use and will be provided sterile for single use applications. The material of construction, cutting action, availability of suction and tip configuration are equivalent to currently marketed products. As proven in arthroscopic applications, this design offers the required precision for controlling the location and extent of tissue resection.

The Thermo-Plastic Shaver Blades will use materials deemed to be biocompatible per ISO 10993 and the General Program Memorandum #G95-1. The disposable shaver blade is Gamma sterilized per AAMI ST32, SAL 10⁻⁶. Packaging is validated per ASTM standards 4169, D999, D775, F88, D3078.

The Stryker Thermo-Plastic Shaver Blades do not raise any new safety and efficacy concerns when compared to a similar device marketed by Linvatec. Therefore, the Stryker Thermo-Plastic Shaver Blades is substantially equivalent to the Linvatec, Merlin Polyblade shaver.

Eric Finley
Design Engineer

Enclosure