

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

**510(k) Summary of
Safety and Effectiveness**

Information supporting claims of substantial equivalence as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: Mitek Electrosurgical System for Arthroscopic Use

PREDICATE DEVICE NAME: ArthroCare Arthroscopic Electrosurgical System

510(K) SUMMARY

Device Description

The Mitek Electrosurgical System is comprised of four components: the electrosurgical generator, a footswitch, a handpiece with a cable to connect to the generator and five types of electrode tip configurations are used in the arthroscopic procedure.

Intended Use

The Mitek Electrosurgical System is intended for resection, ablation and excision of soft tissue, and hemostasis of blood vessels in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist.

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Mitek Electrosurgical System for Arthroscopic Use
Mitek Products

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

**Indications
Statement**

The Mitek Electrosurgical System is intended for soft tissue resection, ablation, and excision and hemostasis of blood vessels in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist.

**Technological
Characteristics**

The new device is technologically the same as the predicate device. Both devices use high frequency electrosurgical current to achieve the intended clinical purpose. A single pair of electrode is used in the new device, while the predicate device uses multiple electrodes. This difference does not raise any new question of safety and effectiveness.

Performance Data

Preclinical and laboratory cadaveric evaluations were conducted to show that the device functions as intended. In preclinical and cadaveric evaluations, the ArthroCare Arthroscopic Electrosurgical System was used for comparison. Clinical data was deemed unnecessary to support the Premarket Notification. Sufficient data has been obtained from preclinical and cadaveric testing to assess safety and effectiveness characteristics of the device when compared to the predicate device.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.

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