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510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date prepared: June 17, 1996

Submitter: Midas Rex Pneumatic Tools Inc.
3001 Race Street
Fort Worth, Texas 76111
(817) 831-4181

Contact Person: Michael Fowler
Director Regulatory Affairs

Trade (proprietary) Name: Midas Rex Motor (Midas III)

Common / Classification Name: Pneumatic Cranial Drill Motor

Device Classification: Class II

Predicate Device: Midas Rex Motors,
Midas (I, II, & Convertible) K953434 Class II
Midas (I, II, & Convertible) K952300 Class I
Whirl Wind TM (Pre-1976)

Predicate Attachments: Midas GS and GS20 Surgical Tool System
K952463 Class I
Midas Drill Guide Attachment
K954076 Class I
Midas Telescoping System K953433 Class I

Description Of the Device:

Ergonomically, designed lightweight motor featuring small, overall diameter for comfort and ease of handling. The Midas Rex III motor operates at variable speeds. Operating pressures range from 20-150 psi (2-10 bar), with a suggested operating pressure of 100 psi (6.9 bar).

The Midas Rex III has a standard quick disconnect GS dissecting tool and tube attachment system, which includes a fixed or rotating footed attachment, the telescoping microsystems, and the micro mini drill guide.

Statement of Intended Use:

The Midas Rex Motor is designed for skull base and other microsurgical applications, including otolaryngology, ear, nose and throat, craniofacial and maxillofacial specifications in which a small, lightweight, high speed bone dissection system is desired.

Technological Characteristics:

The modified device has the same technological characteristics (i.e., design, material, energy source) as the predicate device. The specifications are as follows: