

K953434

510 (k) SUMMARY

MAY 16 1995

I. ADMINISTRATIVE

Submitter: Midas Rex Pneumatic Tools, Inc.
3001 Race Street
Fort Worth, Texas 76111
(817) 831-2604

Contact Person: Forest Barber, Jr.

Date of Preparation: July 20, 1995

II. DEVICE NAME

Proprietary Name: Midas Rex Motors (Midas I, Midas II and Convertible Models)

Common Name: Surgical Instrument Motor

Classification Name: Pneumatic Cranial Drill Motor (84HBB)

III. PREDICATE DEVICE

Midas Rex Whirlwind™ Motor, legally marketed prior to May 28, 1976.

IV. DEVICE DESCRIPTION

The Midas Rex Motors (Midas I, Midas II and Convertible models) are air-powered, rotating motors designed to operate at 20-120 psi or at up to 200 psi. The motor is connected to an air-supply source by means of a stainless steel joint and a plastic air hose with inner rubber pressure hose.

The motors are constructed of stainless steel, aluminum and brass and are designed to operate at 20-120 psi or at up to 200 psi with the same performance characteristics. Depending on user preference, the 200 psi motor is available in either a round or hexagonal casing, approximately 0.75 inch in diameter. Similarly, the 120 psi motor can be supplied in either a round or hexagonal casing in diameters of approximately 0.375, 0.5 or 0.75 inch.

Again depending on user preference, the joint connecting the motor to the air hose can be equipped with a rotating cuff at one or both ends, allowing the motor and/or air hose to swivel independently with respect to the joint, thus providing greater freedom of movement during surgical procedures and avoiding possible "kinking" of the air hose. Thus, a variety of device configurations are possible based on the surgeon's personal preference, as shown below:

	Motor	Joint	Hose
Midas I	Fixed Swivels	Straight (180°) Straight (180°)	Fixed Swivels
Midas II	Fixed Fixed Swivels Swivels	Angled (45°) Angled (45°) Angled (45°) Angled (45°)	Fixed Swivels Fixed Swivels
Convertible	Fixed Fixed Swivels Swivels	180° or 45° 180° or 45° 180° or 45° 180° or 45°	Fixed Swivels Fixed Swivels

Midas Rex Motors are supplied non-sterile for sterilization by hospital staff immediately prior to each use. The materials of construction of the motor and air hose are compatible with both ethylene oxide and steam sterilization (flash or standard autoclave procedures). A 4-minute cycle is recommended for high vacuum steam sterilization at 270° F. Gravity displacement steam sterilization may be performed at 250° F for 35 minutes or at 270° F for 15 minutes. A minimum of 18 hours mechanical aeration is recommended following ethylene oxide sterilization.

V. INTENDED USE

To provide power to operate removable rotating surgical cutting tools or drill bits on a patient's skull.

VI. COMPARISON TO PREDICATE DEVICES

See Table.

Table of Comparison to Legally Marketed Device

	Midas I	Midas II	Convertible	Midas I, II and Convertible (K952300)	Whirlwind™ (pre-1976)
Construction	Stainless steel, brass and aluminum	Stainless steel, brass and aluminum			
Case Shape/Diameter	Round or hexagonal: 0.375, 0.5 or 0.75 inch	Round or hexagonal: 0.375, 0.5 or 0.75 inch	Round or hexagonal: 0.375, 0.5 or 0.75 inch	Round or hexagonal: 0.375, 0.5 or 0.75 inch	Round/0.75 inch
Motor/Air hose Joint	Straight	Angled (45°)	Straight or Angled (swivel joint)	Straight, Angled and Swivel Joint	Straight
Motor Alignment (relative to joint)	Fixed or Swivel	Fixed or Swivel	Fixed or Swivel	Fixed or Swivel	Fixed
Hose Alignment (relative to joint)	Fixed or Swivel	Fixed or Swivel	Fixed or Swivel	Fixed or Swivel	Fixed
Air Operating Pressure	20-120 psi or 200 psi	200 psi			
RPM (000's)	40-75 (20-120 psi) 30-75 (200 psi)	30-75			
Stall Torque	1-5.3 (20-120 psi) 1.3-5.3 (200 psi)	1.3-5.3			
Intended Use	To provide power to operate removable rotating surgical cutting tools or drill bits on a patient's skull.	To provide power to operate removable rotating surgical cutting tools or drill bits on a patient's skull.	To provide power to operate removable rotating surgical cutting tools or drill bits on a patient's skull.	To provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue.	To provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue.