SEP 1 2 1997

K972289

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date prepared: June 18, 1997

Submitter:

Midas Rex, L. P.
3001 Race Street
Fort Worth, Texas 76111
(817) 831-4181

Contact Person:

Michael Fowler
Director Regulatory Affairs

Trade (proprietary) Name: Midas Rex Motor
Model (MRIV)

Common / Classification Name: Pneumatic Cranial Drill Motor
Regulation no. 882.4370
Product code 84 HBB
Device Classification: Class II

Predicate Device: Midas Rex Motors, Midas I, Midas II & Convertible K 953434

Description of the Device: The Midas Rex MRIV motor is an Ergonomically, designed lightweight variable speed motor, with a small overall diameter. The motor provides pneumatic power to operate removable attachments and rotating surgical dissecting tools. The motor operates at variable speeds on operating pressures range from 20-150 psi.

Statement of Intended Use:

The Midas Rex MRIV pneumatic motor is designed for skull based and other microsurgical applications.

Technological Characteristics:

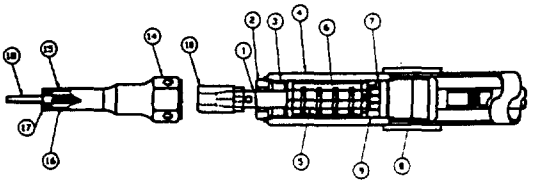
The Midas Rex MRIV motor, attachments and accessories have the same technological characteristics in design properties and features, quality and energy source as the predicate devices. The material of several of the components has been changed to non- magnetic material.

The material specifications are as follows:

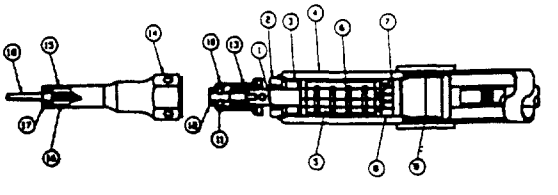
MATERIAL LIST

	ITEM #	WHIRLWIND	MRIV	MRIV (OPTIONAL)
MOTOR	1	400 SERIES STAINLESS STEEL	TITANIUM ALLOY	300 SERIES STAINLESS STEEL
	2	YELLOW BRASS	TITANIUM ALLOY	YELLOW BRASS
	3	BEARING	BEARING	BEARING
	4	ALUMINUM ALLOY	ALUMINUM ALLOY	ALUMINUM ALLOY & POLYPHENYLSULFONE OR POLYAMIDE
	5	PHENOLIC CELLULOSE IMPREGNATION	PTFE POLYAMIDE-IMIDE	NONE
	6	PRECIP. HARDENABLE STAINLESS STEEL	TITANIUM ALLOY	300 SERIES STAINLESS STEEL
	7	YELLOW BRASS	YELLOW BRASS	NONE
	8	ALUMINUM ALLOY	ALUMINUM ALLOY	NONE
	9	BEARING	BEARING	BEARING
COLLET (ASS'Y)	10	400 SERIES STAINLESS STEEL	TITANIUM ALLOY	POLYPHENYLSULFONE (OR POLYAMIDE) & 400 SERIES STAINLESS STEEL
	11	NONE	CERAMIC	NONE
	12	NONE	TITANIUM ALLOY	NONE
	13	NONE	PHOSPHOROUS BRONZE	NONE
ATTACHMENTS BASE	14	ALUMINUM ALLOY	TITANIUM ALLOY	ALUMINUM ALLOY
TUBE	15	300 SERIES STAINLESS STEEL	TITANIUM ALLOY	300 SERIES STAINLESS STEEL
SPACER	16	ALUMINUM ALLOY	ALUMINUM ALLOY	POLYPHENYLSULFONE OR POLYAMIDE
BEARING	17	BEARING	BEARING	BEARING
TOOLS	18	TOOL STEEL	TITANIUM ALLOY	300 SERIES STAINLESS STEEL W/TIN, ZrN OR TiAlN COATINGS

WHIRLWIND MOTOR/ ATTACHMENT/ TOOL



MRIV MOTOR/ ATTACHMENT/ TOOL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 1997

Mr. Michael Fowler
Director of Regulatory Affairs
Midas Rex Pneumatic Tools, Inc.
3001 Race Street
Fort Worth, Texas 76111-4117

Re: K972289
Trade Name: Midas Rex Motor
Regulatory Class: II
Product Code: 84HBB
Dated: June 18, 1997
Received: June 19, 1997

Dear Mr. Fowler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

June 18, 1997

510(K) Number:

Device Name: Midas Rex Motor

Indications for Use:

The Midas Rex MRIV pneumatic motor provides power to operate an assortment of rotating surgical cutting tools. The motor is intended for skull based bone dissection and other microsurgical applications, including specialties in which a lightweight, high-speed bone dissecting system can be used in or near a magnetic field.

Name: Midas Rex MRIV Motor
Regulation no: 882.4370
Product code: 84 HBB
Class II

Michael Fowler
Director of Regulatory Affairs

Prescription Use ✓ OR Over The Counter Use _____
(Per 21 CFR 801.109)

Thomas J. Callahan
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972289