K030857

OCT 16 2003

510 (k) Summary of Safety and Effectiveness

DEVICE NAME:	MAHE Pediatric Naso Pharyngoscope its associated and ancillary equipment and endoscopic accessories
COMMON/USUAL NAME	Pediatric Naso-Pharyngoscope and Accessories
CLASSIFICATION NAME	Pediatric Naso-Pharyngoscope and Accessories
PREDICATE DEVICES	KARL STORZ NASOPHARYNGOSCOPE (FLEXIBLE OR RIGID) K945381
SUBMITTED BY:	Paul Cart MAHE International Inc 490 Craighead St Nashville, TN 37204 615-269-7256
ESTABLISHMENT #	9007726

The MAHE **Pediatric** Naso-Pharyngoscope is intended for use only by qualified surgeons. Do not use the instrument for any purpose other than its intended application.

The MAHE **Pediatric** Naso-Pharyngoscope has been designed to be used with a light source, documentation equipment and video monitor for sinuscopy diagnosis and treatment within the nasal cavity and nasal pharynx.

The MAHE **Pediatric** Naso-Pharyngoscope is indicated for visual exam during diagnostic and therapeutic procedure within the nasal cavity and nasal pharynx.

The MAHE **Pediatric** Naso-Pharyngoscope are designed, manufactured, and tested according to Voluntary Safety Standards IEC 601-1 and IEC 601-2-18.

When compared with the predicate devices, the MAHE **Pediatric** Naso-Pharyngoscope does not incorporate any significant change in intended use, method of operation, material, or design that could affect the safety or effectiveness.

Only physicians who have received thorough previous training in the art of flexible sinuscopy should use this instrument.

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Predicate Device Comparison

Feature	New Device	Predicate
Optical System		
Field of view	95 degree	80+/-4 degree
Depth of view	3-50mm	3-50mm
Working length	300-420mm	320mm
Sheath		
Shaft	2.7mm	2.7 mm
Distal end	2.8mm	2.8 mm
Material	Identical	Identical
Bending Section		
Up	120	160+3,-10
Down	100	130 +5,-10
Sterilization Method(s)		
Weight	not more than 0.8 kg	.5-.7 kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

MAHE International, Inc.
c/o Paul Cart
490 Craighead
Nashville, TN 37204

Re: K030857
Trade/Device Name: MAHE Pediatric Naso Pharyngoscope its associated and Ancillary equipment and endoscopic accessories
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: September 24, 2003
Received: September 24, 2003

Dear Mr. Cart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT FOR INDICATIONS FOR USE

510 (k) Number : K030857

Device Name: MAHE International Pediatric NASOPHARYNGOSCOPE

Indications for Use:

The MAHE International Pediatric NASOPHARYNGOSCOPE is indicated for visual examination during a diagnostic and therapeutic procedure within the nasal cavity and nasal pharynx.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRD, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
And Radiological Devices

510(k) Number: K030857

Prescription Use: ✓ **OR Over-the-Counter Use:** _____

(Per 21 CFR 801.109)