MAY 2 3 2000

K000108

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

Regulatory & Marketing Services, Inc. (RMS)
3234 Ella Lane
New Port Richey, FL 34655

Phone: 813-645-2855
Fax: 813-645-2856

Contact Person: Art Ward

Date of Summary: May 8, 2000

Trade Name: BHK Holding Nasal Catheter

Classification Name: Balloon, Epistaxis

Predicate Device: Xomed- Epistat Nasal Catheter-K943718

Device Description/ Comparison:

Nasal Catheter- Anterior and Posterior Epistaxis
The following chart provides a comparative summary of the BHK product and predicate device.

K000108

Comparative Chart:

Epistaxis Nasal Catheter	BHK Holding-Rapid Rhino	Xomed- Epistat I and II
Length	90/100mm	95mm
Diameter	10mm	10mm
Catheter Material	PVC	Silicone
Anterior Cuff	Yes	Yes
Posterior Cuff	Yes	Yes
Safety Cuff	Yes	No
Sterile	Yes	Yes
Single Use	Yes	Yes
Catheter Airway	Yes	Yes
Epistaxis Control Material	Yes	Epistat II- Yes
Hemostatic Material	Carboxymethylcellulose	Merocel

Intended Use:

The Rapid Rhino is designed to control epistaxis, due to: a) trauma, b) post-operative bleeding, c) spontaneous epistaxis. It is intended to treat minor nasal bleeding.

Biocompatibility:

Biocompatiblility studies for the materials included in this submission have been completed. A copy of the Biocompatiblity study completed is enclosed in the 510K.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2000

Mr. Arthur J. Ward
Regulatory & Marketing Services, Inc.
3234 Ella Lane
New Port Richey, FL 34655

Re: K000108
Trade Name: BHK Holding- Rapid Rhino Nasal Balloon Catheter
Regulatory Class: I
Product Code: 77EMX
Dated: March 28, 2000
Received: March 29, 2000

Dear Mr. Ward:

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 current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K000108

Device Name: BHK Holding- Rapid Rhino Nasal Balloon Catheter

Indications For Use:

The Rapid Rhino is designed to control epistaxis, due to: a) trauma, b) post-operative bleeding, c) spontaneous epistaxis. It is intended to treat minor nasal bleeding.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000108

Division Sign-Off
Division of Ophthalmic Devices
510(k) Number

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

(Optional Format 1-2-96)