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Summary of Safety and Effectiveness Data

NOV - 4 2010

The Byrne Medical DEFENDO™ Disposable Air/Water Valve is intended to be used to control the air/water function of an endoscope during a GI endoscopic procedure.

The Byrne Medical DEFENDO™ Disposable Air/Water Valve is substantially equivalent to the Olympus® MH-438 Air/Water Valve. The following table is a comparison between the two:

Table 14-1: Comparison of features and principles of operation between the DEFENDO™ Disposable Air/Water Valve and Predicate Device (Olympus®MH-438 Air/Water Valve, K001241)

Characteristic	Byrne Medical	Olympus®	Same?
Part number	100304	MH-438	N/A
Trade Name	100304: DEFENDO™ Disposable Air/Water Valve	Olympus® EVIS EXERA Colovideoscopes	N/A
510(k) Document Number	This submission	K001241	N/A
Product Code	KOG	FDF	No
Regulation Number	876.1500	876.1500	Yes
Class	II	II	Yes
Review Advisory Committee	Gastroenterology/Urology	Gastroenterology/Urology	Yes
Indications for use	The DEFENDO™ Disposable Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.	The Olympus® Air/Water valve is intended to be used to control the air/water function on an Olympus ®endoscope during a GI endoscopic procedure.	Yes
Sterile	Yes	No, user must sterilize	No
Single Use	Yes	No, re-sterilize, re-use	No
Compatible Endoscope(s)	Olympus® 140/160/180/240/260 series endoscopes	Olympus® 140/160/180/240/260 series endoscopes	Yes
Patient Population	Male/Female, Pediatric to Adult	Male/Female Pediatric to Adult	Yes
Reusable or disposable	Disposable	Reuseable	No

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Summary of Safety and Effectiveness Data

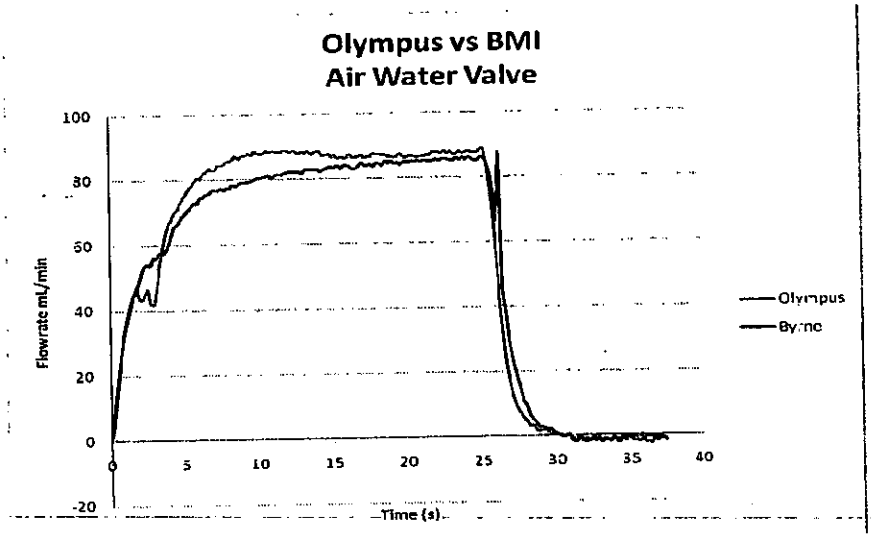
Performance Testing

Comparitive Testing

Water Flow Test

Ten BMI 100304 Air/Water valves and ten Olympus MH-438 Air/Water valves were compared to each other in a side-by-side comparison of flow rates through the endoscope, whereby 188 measurements were made over a time period of 37.4 seconds measuring the rate of flow of water through the scope. Measurements were taken at 0.2 second intervals for comparison and statistical analysis yielded the following:

n = 188
Correlation Coefficient r = 0.989



Additionally, measurements from 0 – 7 seconds were analyzed for comparison, the 0-7 second period is significant as this is the typical amount of time the user utilizes for lens cleaning. The following is a graphical depiction of the results:

n = 36
Correlation coefficient r = 0.96

Olympus vs. Byrne

Based on the above Comparative Testing results and the Bench Testing results (see Bench Testing results, Section 20 of this submission)from the comparison between the Olympus® and the Byrne Medical Air/Water Valves, we have concluded that the Byrne Medical DEFENDO™Disposable Air/Water Valve is substantially equivalent to the Olympus® MH-438 Air/Water Valve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. John Willis
Director of Regulatory Affairs
Byrne Medical Inc.
3150 Pollok Dr.
CONROE TX 77303

NOV - 4 2010

Re: K102409
Trade/Device Name: DEFENDO™ Disposable Air/Water Valve for GI Endoscopes
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscopes and accessories
Regulatory Class: II
Product Code: ODC, FDF
Dated: August 23, 2010
Received: August 24, 2010

Dear Mr. Willis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV - 4 2010

Indications for Use

510(k) Number (if known) K102409

Device Name: DEFENDO™ Disposable Air/Water Valve for GI Endoscopes

Indications for Use:

The DEFENDO™ Disposable Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102409