Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Summary of Safety and Effectiveness Data

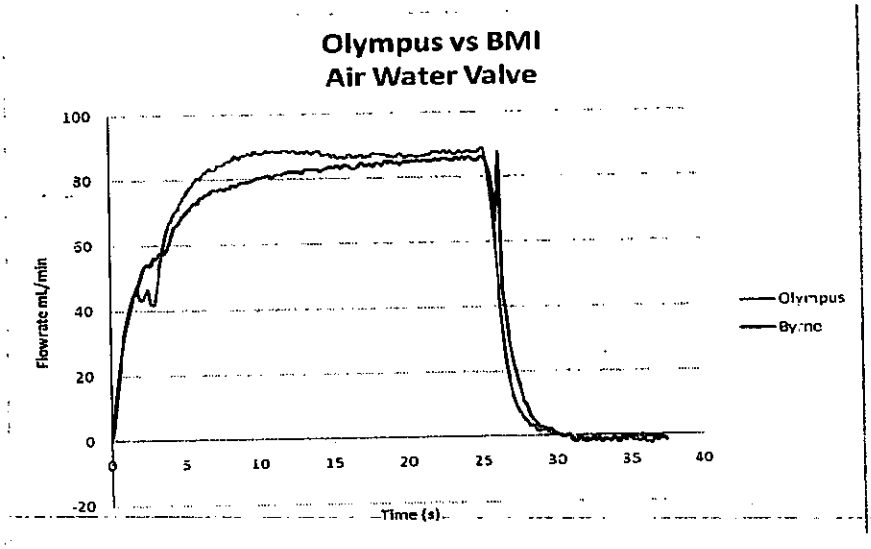
Performance Testing

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

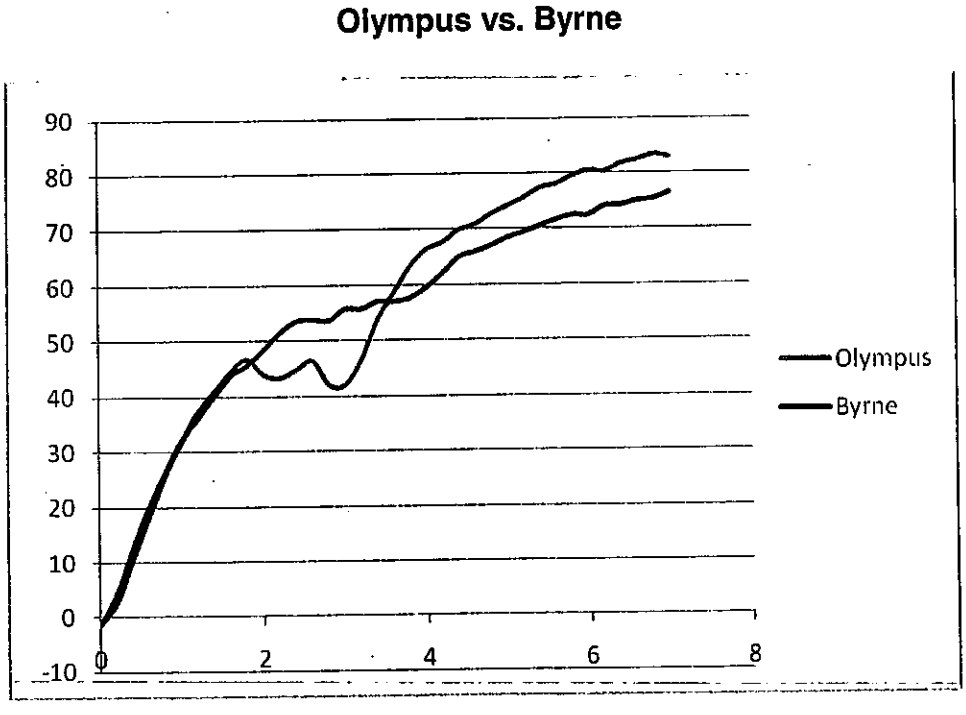


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2207 Released by CDRH on 09-13-2016 9/13

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



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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

MJC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 10/19/10

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K102409/A2

To: Division Director: GU/DRGUD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

✓ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: Mary J Cornelius

Date: 12/10/2010

Add to File

PCC 12/10/10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-2016

K102409/A2

Byrne Medical, Inc.
Infection Control Matters.™
3150 Pollok Dr.
Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

October 14, 2010

FDA CDRH DMC
OCT 19 2010
Received

K-37.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K102409
Additional Information

Dear Sir/Madam:

In the original submission dated August 23, 2010, there was a mistake in Section 15 Labeling. The submitted labeling for the device Pouch and Carton had wording "Manufactured For" Byrne Medical it should have been "Manufactured By" Byrne Medical.

I have included copies of the revised labels.

Manufacturer:	Byrne Medical Inc.
Establishment Registration No.:	1651395

If you need any additional information or have any questions you may call me at 936-521-4240.

Sincerely,

John Willis

John Willis
Director of Regulatory Affairs

jrwillis@byrnemedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Byrne Medical, Inc.
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October 14, 2010

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FDA CDRH DMC
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RE: K102409
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Sincerely,

John Willis

John Willis
Director of Regulatory Affairs

jrwillis@byrnemedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2010-2207; Released by CDRH on 09-13-2013 69/13

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
October 14, 2010	(b)(4)	K102409

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Byrne Medical Inc.	Establishment Registration Number *(if known)*: 1651395
Division Name *(if applicable)*:	Phone Number *(including area code)*: 936-521-4240
Street Address: 3150 Pollok Dr.	FAX Number *(including area code)*: 936-539-2381

City	State / Province	ZIP/Postal Code	Country
Conroe	Texas	77303	USA

Contact Name: John Willis

Contact Title: Director of Regulatory Affairs	Contact E-mail Address: jrwillis@byrnemedical.com

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:	
Division Name *(if applicable)*:	Phone Number *(including area code)*:
Street Address:	FAX Number *(including area code)*:

City	State / Province	ZIP Code	Country

Contact Name:

Contact Title:	Contact E-mail Address:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
PSC Graphics (301) 443-1090 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Response to FDA correspondence:

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	78 FDF	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K001241	1	EVIS EXERA Colonovideoendoscopes	1	Olympus Optical Co., LTD
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Endoscope and Accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	DEFENDO Disposable Air/Water Valve	1	100304
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
KOG	21 CFR 876.1500	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Gastroenterology-urology devices

Indications *(from labeling)*

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207, Released by CDRH on 09-13-20169/13

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)* K102409

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Byrne Medical Inc.		Establishment Registration Number: 1651395	
Division Name *(if applicable)*		Phone Number *(including area code)*: 936-521-4240	
Street Address: 3150 Pollok Dr.		FAX Number *(including area code)*: 936-539-2381	
City: Conroe		State / Province: Texas	ZIP Code: 77303 / Country: USA
Contact Name: John Willis	Contact Title: Director of Regulatory Affairs	Contact E-mail Address: jrwillis@bymemedical.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ASTM F 1980	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Device Packages	2007	04/01/2007
2	ISO 10993-1	ISO	Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing	2003	08/01/2003
3	ISO 10993-5	ISO	Biological Evaluation of Medical Devices-Part 5: Tests for in-vitro Cytotoxicity	1999	05/01/1999
4	ISO 10993-10	ISO	Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Sensitization	2002	09/01/2002
5	ASTM D 6499	ASTM	Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products	2007	11/01/2007
6	ISO 10993-7	ISO	Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals	1995	09/01/1995
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Pouch label

DEFENDO™

DISPOSABLE AIR/WATER VALVE FOR GI ENDOSCOPES

SINGLE USE ONLY
DO NOT REUSE
DO NOT RESTERILIZE

CONSULT INSTRUCTIONS FOR USE

STERILE EO STERILIZED USING ETHYLENE OXIDE

MANUFACTURER

MANUFACTURED BY:
BYRNE MEDICAL, INC
3150 POLLOK DR
CONROE, TX 77303
1-800-490-9869

LD-304-A / REV A

REF 100304

LOT STYEAR-LOT

MM / YYYY

CE 0413

1

QUANTITY: ONE (1)

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Carton label

DEFENDO™

DISPOSABLE AIR/WATER VALVES FOR GI ENDOSCOPES

SINGLE USE ONLY
DO NOT REUSE
DO NOT RESTERILIZE

CONSULT INSTRUCTIONS FOR USE

STERILE EO STERILIZED USING ETHYLENE OXIDE

MANUFACTURER

MANUFACTURED BY:
BYRNE MEDICAL, INC
3150 POLLOK DR
CONROE, TX 77303
1-800-490-9869

LD-304-B / REV A

REF 100304

LOT STYEAR-LOT

MM / YYYY

CE 0413

100

QUANTITY:
ONE HUNDRED (100)

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-2016

K102409 | A1

Byrne Medical, Inc.
Infection Control Matters.™
3150 Pollok Dr.
Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

September 13, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
SEP 17 2010
Received

RE: K102409
Additional Information

12-42

Dear Sir/Madam:

The attached information FDA Form(s) 3654 were inadvertently omitted from the original submission.

Manufacturer:	Byrne Medical Inc.
Establishment Registration No.:	1651395

If you need any additional information or have any questions you may call me at 936-521-4240.

Sincerely,

J. Willis

John Willis
Director of Regulatory Affairs

jrwillis@byrnemedical.com

MKT-012 Revision C

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

11

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Infection Control Matters.™

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Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

September 13, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K102409
Additional Information

Dear Sir/Madam:

The attached information FDA Form(s) 3654 were inadvertently omitted from the original submission.

Manufacturer:	Byrne Medical Inc.
Establishment Registration No.:	1651395

If you need any additional information or have any questions you may call me at 936-521-4240.

Sincerely,

John Willis
Director of Regulatory Affairs

jrwillis@byrnemedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
September 13, 2010	(b)(4)	K102409

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Byrne Medical Inc.	Establishment Registration Number *(if known)*: 1651395		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 936-521-4240		
Street Address: 3150 Pollok Dr.	FAX Number *(including area code)*: 936-539-2381		
City: Conroe	State / Province: Texas	ZIP/Postal Code: 77303	Country: USA
Contact Name: John Willis			
Contact Title: Director of Regulatory Affairs	Contact E-mail Address: jrwillis@byrnemedical.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*:		
Street Address:	FAX Number *(including area code)*:		
City:	State / Province:	ZIP Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

rY

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	78 FDF	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K001241	1	EVIS EXERA Colonovideoendoscopes	1	Olympus Optical Co., LTD
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Endoscope and Accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	DEFENDO Disposable Air/Water Valve	1	100304
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: KOG

C.F.R. Section *(if applicable)*: 21 CFR 876.1500

Classification Panel: Gastroenterology-urology devices

Device Class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Indications *(from labeling)*

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)* K102409

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name Byrne Medical Inc.		Establishment Registration Number 1651395		
Division Name *(if applicable)*		Phone Number *(including area code)* 936-521-4240		
Street Address 3150 Pollok Dr.		FAX Number *(including area code)* 936-539-2381		
City Conroe		State / Province Texas	ZIP Code 77303	Country USA
Contact Name John Willis	Contact Title Director of Regulatory Affairs		Contact E-mail Address jrwillis@byrnemedical.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ASTM F 1980	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Device Packages	2007	04/01/2007
2	ISO 10993-1	ISO	Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing	2003	08/01/2003
3	ISO 10993-5	ISO	Biological Evaluation of Medical Devices-Part 5: Tests for in-vitro Cytotoxicity	1999	05/01/1999
4	ISO 10993-10	ISO	Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Sensitization	2002	09/01/2002
5	ASTM D 6499	ASTM	Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products	2007	11/01/2007
6	ISO 10993-7	ISO	Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals	1995	09/01/1995
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F 1980 Standard Guide for Accelerated Aging of Sterile Medical Device Packages

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-229		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F 1980 Standard Guide for Accelerated Aging of Sterile Medical Device Packages

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
F 1980 - 07	ASTM F 1980 Standard Guide for Accelerated Aging of Sterile Medical Devi	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Accelerated Aging

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
ISO 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing 8/1/2003

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1 BIOLOGICAL EVALUATION OF MEDICAL DEVICES—PART 1: EVALUATION AND TESTING 8/1/2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2.2	Cytotoxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Cytotoxicity testing was selected

DESCRIPTION
Cytotoxicity testing was performed on an EndoGator™ product

JUSTIFICATION
Indirect mucosal membrane contact for limited duration (<24hr)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2.3	Sensitization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Sensitization testing was selected

DESCRIPTION
Sensitization testing was performed on an EndoGator™ product

JUSTIFICATION
Indirect mucosal membrane contact for limited duration (<24hr)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2.4	Irritation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Irritation testing was selected

DESCRIPTION
Irritation testing was performed on an EndoGator™ product

JUSTIFICATION
Indirect mucosal membrane contact for limited duration (<24hr)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
ISO 10993-5 Biological Evaluation of Medical Devices—Part 5: Tests for In-Vitro Cytotoxicity 5/1/1999

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-64	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-5 BIOLOGICAL EVALUATION OF MEDICAL DEVICES—PART 5: TESTS FOR IN-VITRO CYTOTOXICITY 5/1/1999

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.2	Extraction Vehicle	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
option a) (b)(4) [redacted] was selected

DESCRIPTION
(b)(4) [redacted]

JUSTIFICATION
(b)(4) [redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.3.2	recommended extraction conditions are:	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
Option (b))(4) [redacted]

DESCRIPTION
(b)(4) [redacted]

JUSTIFICATION
(b)(4) [redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.3	(b)(4) [redacted]	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4) [redacted]

DESCRIPTION
(b)(4) [redacted]

JUSTIFICATION
Chosen based on the nature of the sample, potential site of use and the nature of use.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
ISO 10993-10 Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Sensitization 9/1/2002

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-10 BIOLOGICAL EVALUATION OF MEDICAL DEVICES—PART 10: TESTS FOR IRRITATION AND SENSITIZATION 9/1/2002

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.3	(b)(4) [redacted]	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
No deviations.

DESCRIPTION
Standard tests were performed on albino rabbits as described by the standard.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.1	(b)(4) [redacted]	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
(b)(4) [redacted]

DESCRIPTION
(b)(4) [redacted]

JUSTIFICATION
(b)(4) [redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.2	Choice of test sample concentrations	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
(b)(4) [redacted]

DESCRIPTION
(b)(4) [redacted]

JUSTIFICATION
Standard methods.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-76		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 7	Ethylene Oxide Sterilization Residuals	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

comply with requirement

DESCRIPTION

EtO residuals for a limited exposure (a) medical device with limits of <20mg EtO and <12mg ECh (ethylene chlorohydrin)

JUSTIFICATION

comply with standard

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1: 2007 Sterilization of health care products-Ethylene oxide - Part 1

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-228		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11135-1: 2007 Sterilization of health care products-Ethylene oxide - Part 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 1	Requirements for development, validation and routine control of a sterilizatio	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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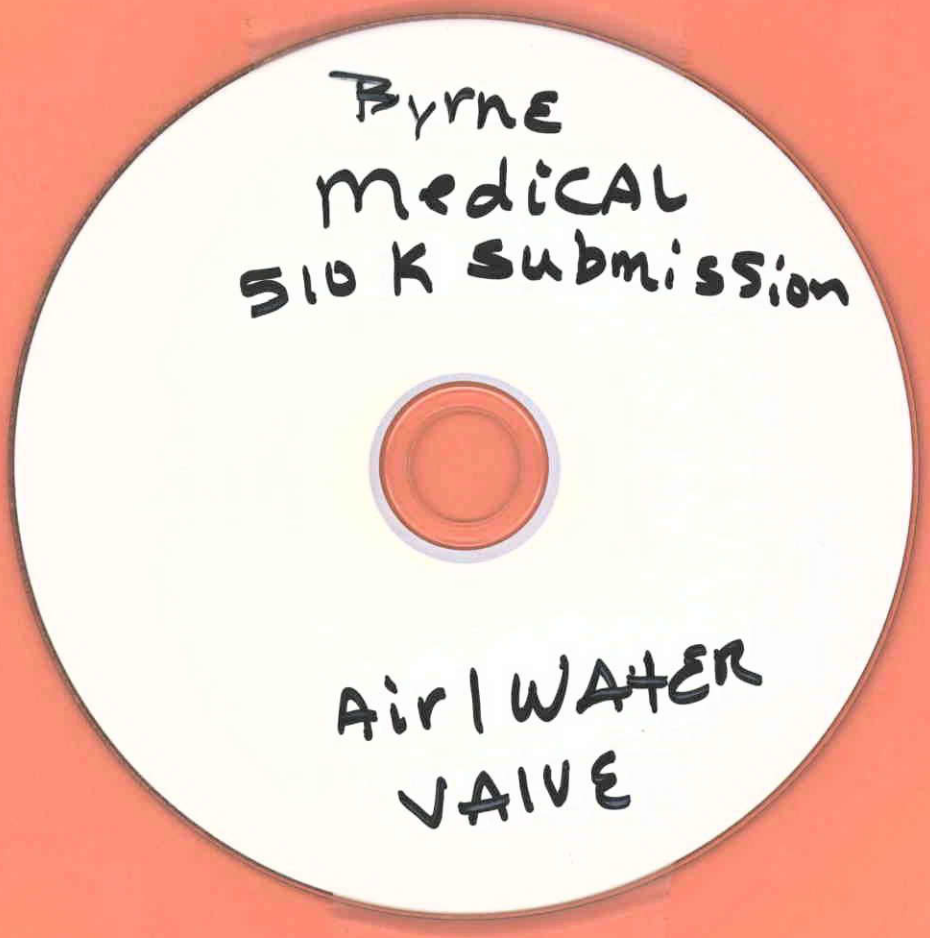

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 25, 2010

BYRNE MEDICAL INC.
3150 POLLOK DR
CONROE, TEXAS 77303
UNITED STATES
ATTN: JOHN WILLIS

510k Number: K102409
Received: 8/24/2010
Product: DEFENDO DISPOSABLE AIR/WATER V

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

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Byrne Medical, Inc.
Infection Control Matters.™

3150 Pollok Dr.
Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

K102409

August 23, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
AUG 24 2010
Received

RE: 510(k) Notification
Traditional

Dear Sir/Madam:

This is to notify you of the intention of Byrne Medical Inc., to commercially market the below listed medical device:

Manufacturer:	Byrne Medical Inc.
Establishment Registration No.:	1651395
Common /Usual Name:	Air/Water Valve
Proprietary Name:	DEFENDO™ Disposable Air/ Water Valve Byrne Medical Part No. 100304
Classification Name:	Endoscope and accessories
Product Code:	KOG
Regulatory Class:	II
Regulation Number:	876.1500
Reason for 501(k):	New disposable single use device
Predicate Device 510(k) No.:	K001241
Predicate Device Trade Name:	Olympus EVIS EXERA Colonovideoscope CF-Q160 AL/I
Predicate Device Product Code:	78 FDF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Byrne Medical, Inc.
Infection Control Matters.™
3150 Pollok Dr.
Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

Design and Use of the Device

Question	Yes	No
Is the device intended for Prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for Over-the-Counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from animal tissue or other biological source?		√
Is the device provided sterile?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device require reprocessed validation data?		√
Does this device contain a drug?		√
Does this device contain a biologic?		√
Does this device use software?		√
Does the submission include clinical information?		√
Is this device implanted?		√

If you need any additional information or have any questions you may call me at 936-521-4240.

Sincerely,

John Willis

John Willis
Director of Regulatory Affairs

jrwillis@byrnemedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cover Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Byrne Medical, Inc.
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August 23, 2010

U.S. Food and Drug Administration
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RE: 510(k) Notification
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Classification Name:	Endoscope and accessories
Product Code:	KOG
Regulatory Class:	II
Regulation Number:	876.1500
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Predicate Device Product Code:	78 FDF

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Main Line: (936) 539 - 0391
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Design and Use of the Device

Question	Yes	No
Is the device intended for Prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for Over-the-Counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from animal tissue or other biological source?		√
Is the device provided sterile?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device require reprocessed validation data?		√
Does this device contain a drug?		√
Does this device contain a biologic?		√
Does this device use software?		√
Does the submission include clinical information?		√
Is this device implanted?		√

If you need any additional information or have any questions you may call me at 936-521-4240.

Sincerely,

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Other

This Section is Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Traditional 510(k) Submission

For

DEFENDO™ Disposable Air-Water Valve

Model # 100304

21 CFR § 876.1500

KOG – Class II

August 23, 2010

Byrne Medical, Inc.

3150 Pollok Rd.
Conroe, Texas 77303
396-539-0391

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Traditional 510(k) – Defendo™ Air/Water Valve

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23. Other

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Financial Certification or Disclosure Statement

This Section is Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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MDUFMA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

Byrne Medical, Inc.
3150 Pollok Drive
Conroe TX 77303
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****5918

2. CONTACT NAME
John Willis

2.1 E-MAIL ADDRESS
jrwillis@byrnemedical.com

2.2 TELEPHONE NUMBER (include Area code)
936-521-4240

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
936-521-2381

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD100100

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted] John Willis 8-23-10 17-Aug-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Declarations of Conformity and Summary Reports

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	Standards #	Standards Org.	Standards Title	Version	Date
	ASTM F 1980	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Device Packages	2007	4/1/2007
	ISO 10993-1	ISO	Biological Evaluation of Medical Devices— Part 1: Evaluation and Testing	2003	8/1/2003
	ISO 10993-5	ISO	Biological Evaluation of Medical Devices— Part 5: Tests for In-Vitro Cytotoxicity	1999	5/1/1999
	ISO 10993-10	ISO	Biological Evaluation of Medical Devices— Part 10: Tests for Irritation and Sensitization	2002	9/1/2002
	ASTM D 6499	ASTM	Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products	2007	11/1/2007
	ISO 10993-7	ISO	Biological Evaluation of medical Devices— Part 7: Ethylene oxide Sterilization Residuals	2008	10/15/2008
	ISO 11135-1	ISO	Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices	2007	4/27/2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Executive 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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 ®160 series endoscopes.	Olympus® 160 series endoscopes	Yes
Patient Population	Male/Female, Pediatric to Adult	Male/Female Pediatric to Adult	Yes
Reusable or disposable	Disposable	Reuseable	No

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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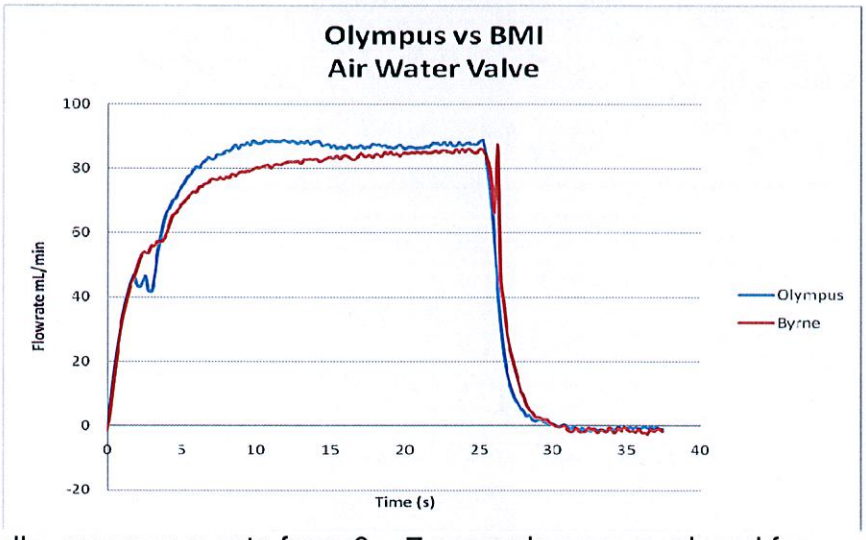
Performance Testing

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 linear regression 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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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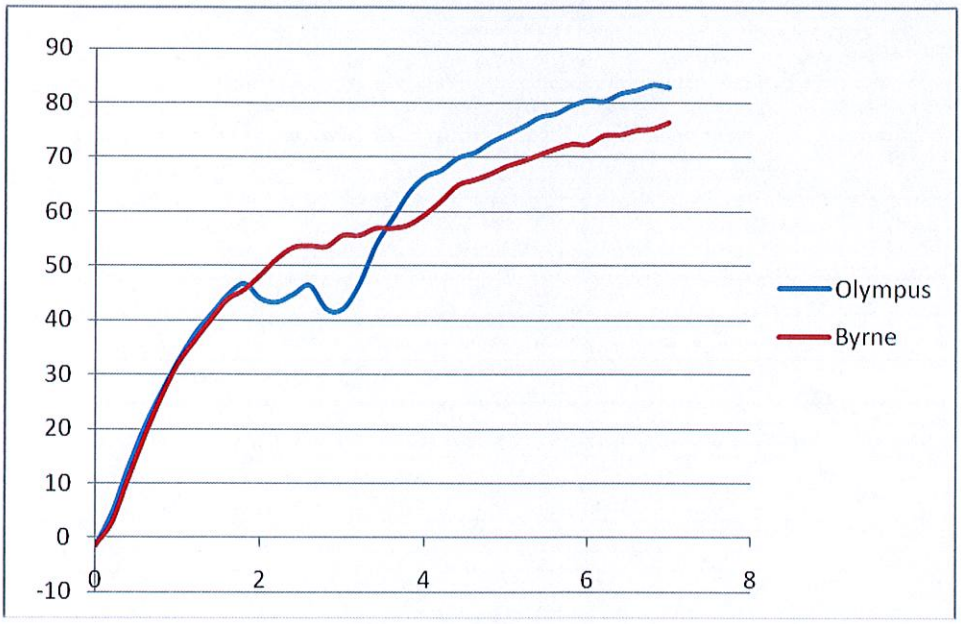
Olympus vs. Byrne



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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Checklist

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm			
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf			
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm			
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm			
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm			
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm			
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm			
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm			
Proposed Labeling	Device Advice " Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm			
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm			
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm			
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm			

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf			
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**			
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm			

Last Updated: 9/3/08 – Brandi Stuart

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Device Description

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

The Byrne Medical DEFENDO™ Disposable Air/Water valve is a single use disposable device. The DEFENDO™ Disposable Air/Water valve is a trumpet valve which allows the user, with the tip of a finger, to control the air/water function on an endoscope. By placing the tip of a finger over the hole on top, it allows air to flow through the endoscope allowing for insufflation of the colon. By depressing the valve, water is allowed to flow into the endoscope allowing for distal lens cleaning.

The DEFENDO™ Disposable Air/Water valve is an injection molded thermal plastic polycarbonate with thermo plastic elastomers and a passivated stainless steel spring..

The DEFENDO™ Disposable Air/Water valve is manufactured at Byrne Medical Inc., in Conroe, Texas and is sterilized by Ethylene Oxide by a contract sterilizer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Schematic Drawings

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Class III Summary and Certification

This Section is Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Substantial Equivalence Discussion

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Substantial Equivalence Discussion

The Byrne Medical, Inc., DEFENDO™Disposable Air/Water Valve and predicate device (Olympus® MH-438 Air/Water Valve, K001241) are in Class II, 21 CFR 876.1500 with Advisory Committee of Gastroenterology/Urology.

The predicate device Olympus® - Air/Water Valve (K001241) is manufactured by Olympus® Optical Co. Ltd. Tokyo, Japan.

The Byrne Medical, Inc., DEFENDO™ Disposable Air/Water Valve has been determined to meet the equivalence decision making process as detailed by the "510(k) Substantial Equivalence Decision-Making Process Flowchart".

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Schematic Drawings

Testing:
The DEFENDO™ Disposable Air/Water Valve testing was conducted under FDA recognized standards.

Similarities and Differences:

Indications for Use
Both products are attached to the air/water cylinder of the endoscope. When the hole on the valve top is covered they provide air to the endoscope for colon insufflation. When the valve is depressed, they feed water onto the objective lens of the endoscope for lens cleaning.

Other

The DEFENDO™Disposable Air/Water Valve and its predicate have the same regulation number and class, the same patient population and environment of use.

Neither the predicate nor the Byrne Air/Water valve come in direct contact with the patient. Indirect contact is made by the passing of air/water through the" *through hole*" in the valve stem.

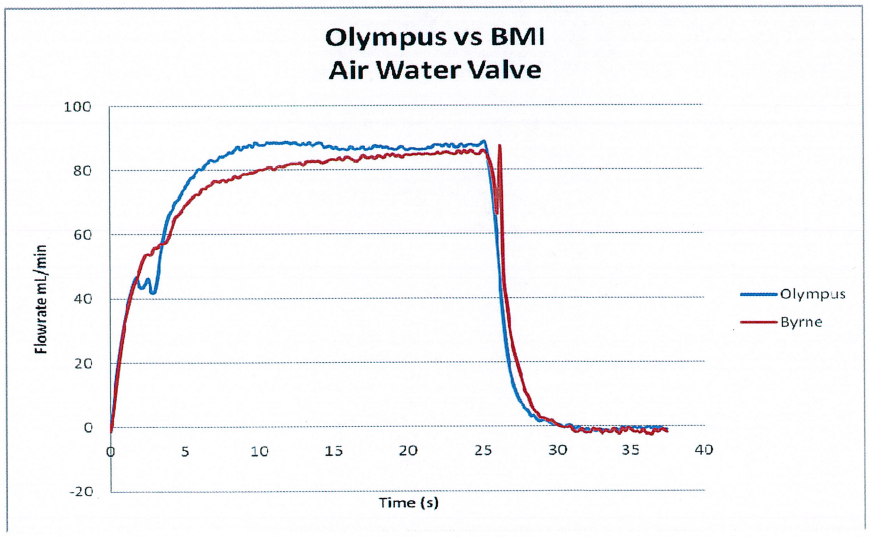
Comparitive Testing

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

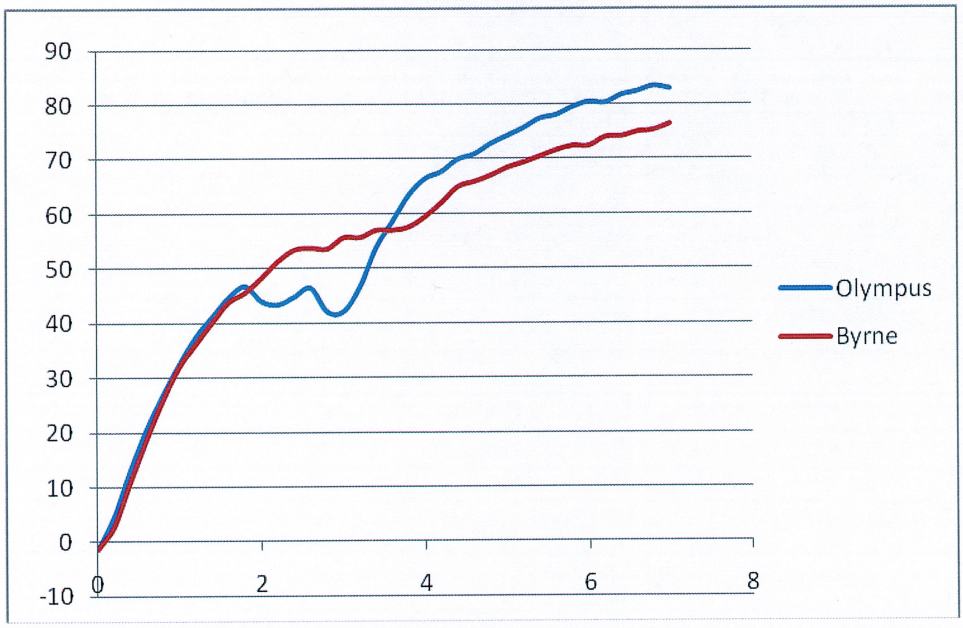


Additionally, measurements from 0 – 7 seconds were analyzed for comparison, the 0-7 second period is significant as this is the typical amount of time the user utilizes for lens cleaning. The following is a graphical depiction of the results:

n = 36

Correlation coefficient r = 0.96

Olympus vs. Byrne



The predicate device labeling (Operation Manual) is included in this section.

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Predicate Device (Olympus) Operation Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-2016

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Proposed Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Draft Labeling

1. Instructions For Use (IFU)
2. Individual Pouch Labeling
3. Shelf Carton Labeling
4. Shipping Case Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-2016

DEFENDO™

Disposable Air/ Water Valve

REF CATALOG NUMBER

DEFENDO™ Disposable Air Water Valve for Olympus® 140/240/160/260/180 Endoscopes #100304

Intended 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.

Warnings and Precautions:

- **Guidelines for Preventing Cross Contamination:**
  - **DO NOT RE-STERILIZE OR REPROCESS.**
  - **The appropriate DEFENDO™ products are to be used with the compatible endoscope, based on scope type/manufacturer.**
  - **DEFENDO™ products must be discarded after each procedure.**
  - **DEFENDO™ products should be discarded prior to the reprocessing of the endoscope.**
  - **DEFENDO™ products should not be refurbished, reprocessed, or re-sterilized.**
  - **Sterility is not guaranteed if package has been opened or damaged. Do not use if packaging or product is damaged.**
  - **Defendo ™ valves are for Single Use Only. Reuse poses a risk of cross contamination of bodily fluids.**
  - **Discard biohazard valves in accordance with local, state, and federal regulations.**
  - **NOTE: If package is damaged or opened prior to intended use, DEFENDO™ products must be discarded immediately.**
  - **Federal (USA) law restricts this device to sale by or on the order of a physician.**
  - **Contact customer service for assistance.**

STERILE EO STERILIZED USING ETHYLENE OXIDE

SINGLE USE ONLY DO NOT REUSE DO NOT RESTERILIZE

Instructions for Use:

1. Open the sterile peel pack and remove the DEFENDO™ Disposable air/water valve.
2. Attach the air/water valve to the air/water cylinder of the endoscope until the valve engages on the air/water cylinder.
3. Cover the hole on the air/water valve to feed air from the air/water nozzle.
4. Prior to the procedure, depress air/water valve to feed water onto the objective lens.
5. At the end of the procedure, leave the air/water valve on the endoscope until it reaches the reprocessing room.

> **WARNING:**
> The air/water valve should remain attached to the endoscope until the endoscopes reaches the reprocessing room to prevent potential cross contamination.

6. Discard the air/water valve after each procedure prior to reprocessing the endoscope

Olympus® is a registered trademark of Olympus Optical Co., Ltd.

MANUFACTURER
Byrne Medical, Inc.
3150 Pollok Drive
Conroe, TX 77303
Phone: 1-800-490-9869
Fax: 936-539-0392
www.byrnemedical.com

CE 0413

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Draft Pouch Labeling

100304

DEFENDO™

DISPOSABLE AIR/WATER VALVE FOR GI ENDOSCOPES

SINGLE USE ONLY
DO NOT REUSE
DO NOT RESTERILIZE

CONSULT INSTRUCTIONS FOR USE

STERILE EO STERILIZED USING ETHYLENE OXIDE

MANUFACTURER

MANUFACTURED FOR:
BYRNE MEDICAL, INC
3150 POLLOK DR
CONROE, TX 77303
1-800-490-9869

LD-304-A / REV A

REF 100304

LOT STYEAR-LOT

MM / YYYY

CE 0413

1

QUANTITY: ONE (1)

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Draft Carton Labeling

100304

DEFENDO™

DISPOSABLE AIR/WATER VALVES FOR GI ENDOSCOPES

SINGLE USE ONLY
DO NOT REUSE
DO NOT RESTERILIZE

CONSULT INSTRUCTIONS FOR USE

STERILE EO STERILIZED USING ETHYLENE OXIDE

MANUFACTURER

MANUFACTURED FOR:
BYRNE MEDICAL, INC
3150 POLLOK DR
CONROE, TX 77303
1-800-490-9869

LD-304-B / REV A

REF 100304

LOT STYEAR-LOT

MM / YYYY

CE 0413

100

QUANTITY:
ONE HUNDRED (100)

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Draft Case Labeling

100304

DEFENDO™

DISPOSABLE AIR/WATER VALVES FOR GI ENDOSCOPES

SINGLE USE ONLY
DO NOT REUSE
DO NOT RESTERILIZE

CONSULT INSTRUCTIONS FOR USE

STERILE EO STERILIZED USING ETHYLENE OXIDE

EC REP

AUTHORIZED REPRESENTATIVE
PARTNERS FOR ENDOSCOPY LLC
MONTROSE HOUSE
MONTROSE STREET
FENTON
STOKE ON TRENT UK
ST43PB
TEL 01782 594164
FAX 01782 323148

MANUFACTURER

MANUFACTURED BY:
BYRNE MEDICAL, INC
3150 POLLOK DR
CONROE, TX 77303
1-800-490-9869

REF 100304

LOT STYEAR-LOT

MM / YYYY

400

QUANTITY:
FOUR HUNDRED (400)

CE 0413

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

LD-304-C / REV A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Sterilization and Shelf Life

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Sterilization and Shelf Life

Sterilization

Before any DEFENDO™ Air/Water Valves are shipped to users, they will be sterilized with ethylene oxide by (b)(4) [redacted]

Sterilization Method

The sterilization method is by exposure to 100% ethylene oxide gas. The process may be more (b)(4) [redacted]

Packaging

Sterile Barrier Packaging for this device consists of a (b)(4) [redacted] pouch comprised of (b)(4) [redacted] (b)(4) [redacted] The sterile barrier package will be (b)(4) [redacted] by Byrne Medical, Inc.

(b)(4) [redacted] will be shipped in (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted]

Maximum Levels of Residuals

Maximum levels of sterilization-related residues will comply with levels established in ISO 10993-7 after two back-to-back sterilizations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

(b)(4) Sterilization

[redacted]

Pyrogens

The device will not be labeled "pyrogen free", so pyrogens will not be tested.

Sterility Assurance level (SAL)

The Sterility Assurance level (SAL) for the device is a minimum of 10^{-6}.

Radiation Dose

The DEFENDO™ Air/Water Valve will not be sterilized by radiation, so radiation does will not be tested.

Shelf Life

Before any DEFENDO™ Air/Water Valve are shipped, they will be subjected to (b)(4) [redacted] testing according to (b)(4) [redacted] (b)(4) [redacted]

Sterile Barrier Packaging for this device consists of (b)(4) [redacted] (b)(4) [redacted] The sterile barrier package will be (b)(4) [redacted]

(b)(4) [redacted] **Test**

Before any DEFENDO™ Air/Water Valve are shipped to customers, they will be subjected to a (b)(4) [redacted] test. (b)(4) [redacted] (b)(4) [redacted] Testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Biocompatibility

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-2016 9/13

Biocompatibility

The Byrne Medical DEFENDO™ Disposable Air/Water Valve is injection molded consisting of thermal plastic polycarbonate, thermal plastic elastomers. And a passivated stainless steel spring.

Materials used in the manufacture are obtained commercially and are biocompatible according to ISO 10993 (Manufacturer's data sheets attached).

Only the polycarbonate and elastomers come in contact with the air/water and have indirect contact with the patient. The stainless steel does not come in contact with the patient either directly or in-directly.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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Software

This Section is Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

19

Electromagnetic Compatibility and Electrical Safety

This Section is Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

20

Performance Testing – Bench

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Byrne Medical, Inc.

3150 Pollok, Conroe Texas, 77303

Bench testing (b)(4) Testing [redacted]

(b)(4) Testing [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Byrne Medical, Inc.

3150 Pollok, Conroe Texas, 77303

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

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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:

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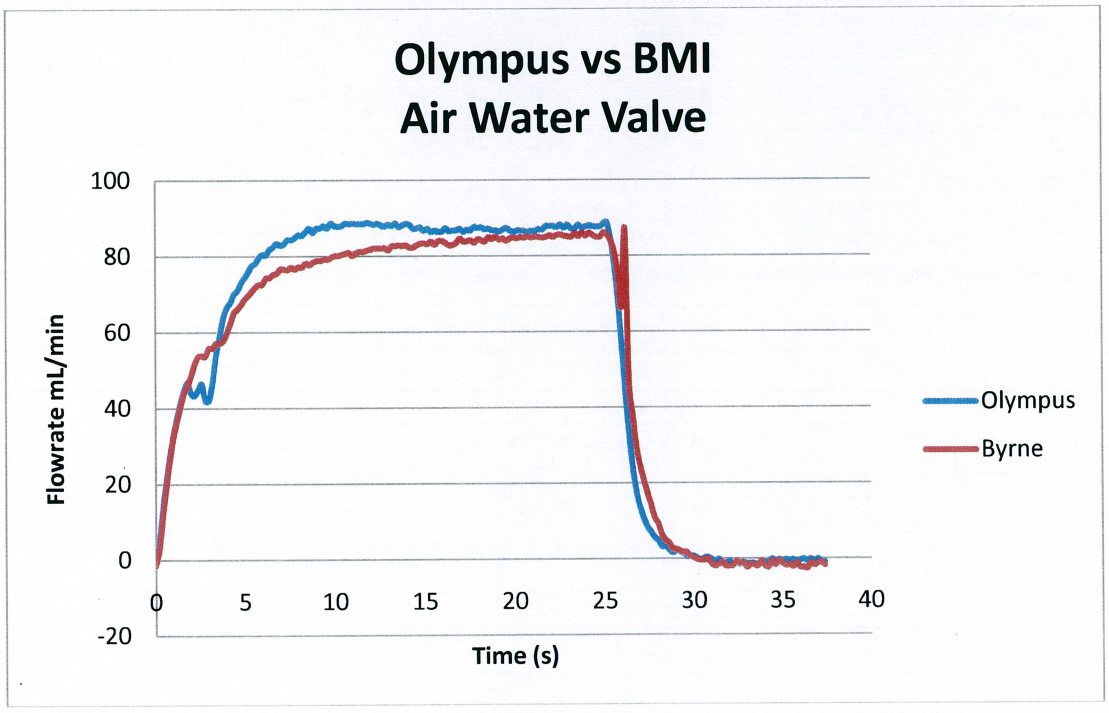

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

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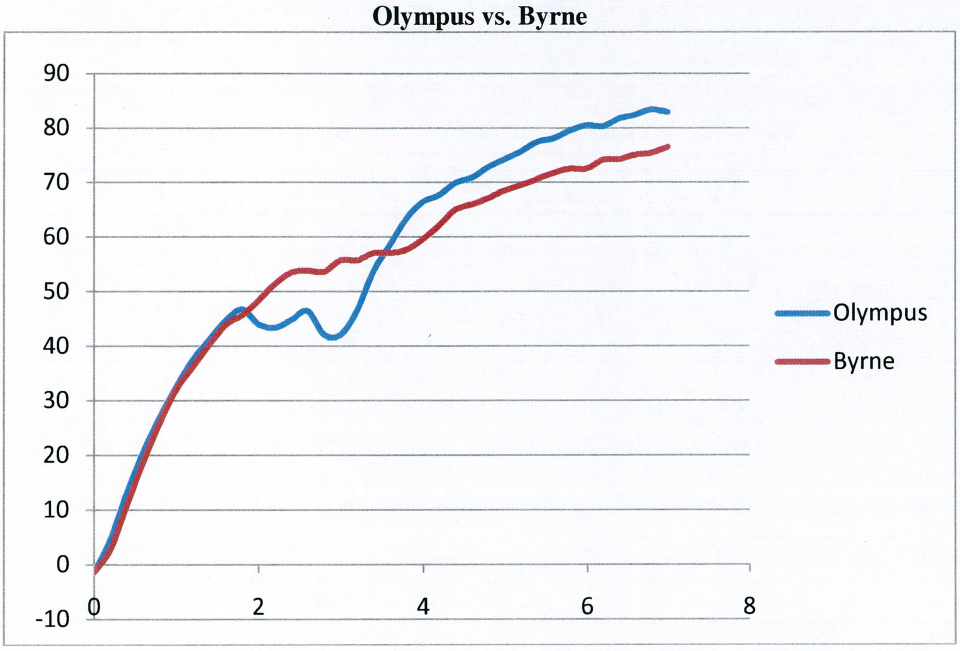

The predicate device labeling (Operation Manual) is included in this section.

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

21

Performance Testing – Animal

This Section is Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Performance Testing—Animal

Animal testing is not necessary to establish the safety or effectiveness of Byrne Medical's DEFENDO® Air/Water valve, or its equivalence to the predicate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

22

Performance Testing – Clinical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-2016/13

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   Byrne Medical Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   August 23, 2010

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   3150 Pollok Dr.
   Conroe, TX 77303

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 936-521-4240
   (Fax) 936-539-2381

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
   FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
   (Attach extra pages as necessary)

   Common/Usual Name: Air/Water Valve
   Model Number: 100304
   Classification Name: Endoscope and Accessories
   Product Code: FDF
   Proprietary Name: DEFENDO Air/Water Valve

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*
   ☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
   ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
   ☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*
    NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
    John Willis

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) John Willis
    (Title) Director of Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    3150 Pollok Dr.
    Conroe, TX 77303

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 936-521-4240
    (Fax) 936-539-2381

15. DATE OF CERTIFICATION
    August 23, 2010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date -** This is the date of the application/submission which the certification accompanies.
3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification -** This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11 -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14. -** Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

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3

CDRH Premarket Review Cover Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
August 23, 2010	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Byrne Medical Inc.	Establishment Registration Number *(if known)*: 1651395		
Division Name *(if applicable)*	Phone Number *(including area code)*: 936-521-4240		
Street Address: 3150 Pollok Dr.	FAX Number *(including area code)*: 936-539-2381		
City: Conroe	State / Province: Texas	ZIP/Postal Code: 77303	Country: USA
Contact Name: John Willis			
Contact Title: Director of Regulatory Affairs	Contact E-mail Address: jrwillis@byrnemedical.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Response to FDA correspondence:

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	78 FDF	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K001241	1	EVIS EXERA Colonovideoendoscopes	1	Olympus Optical Co., LTD
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Endoscope and Accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	DEFENDO Disposable Air/Water Valve	1	100304
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
KOG	21 CFR 876.1500	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Gastroenterology-urology devices

Indications *(from labeling)*

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name: Byrne Medical Inc.		Establishment Registration Number: 1651395		
Division Name *(if applicable)*		Phone Number *(including area code)*: 936-521-4240		
Street Address: 3150 Pollok Dr.		FAX Number *(including area code)*: 936-539-2381		
City: Conroe		State / Province: Texas	ZIP Code: 77303	Country: USA
Contact Name: John Willis	Contact Title: Director of Regulatory Affairs		Contact E-mail Address: jrwillis@byrnemedical.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title		Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ASTM F 1980	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Device Packages	2007	04/01/2007
2	ISO 10993-1	ISO	Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing	2003	08/01/2003
3	ISO 10993-5	ISO	Biological Evaluation of Medical Devices-Part 5: Tests for in-vitro Cytotoxicity	1999	05/01/1999
4	ISO 10993-10	ISO	Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Sensitization	2002	09/01/2002
5	ASTM D 6499	ASTM	Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products	2007	11/01/2007
6	ISO 10993-7	ISO	Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals	1995	09/01/1995
7					

Please include any additional standards to be cited on a separate page.

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Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Indications for Use

510(k) Number (if known)

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary of Safety & Effectiveness Data

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Summary of Safety and Effectiveness Data

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Summary of Safety and Effectiveness Data

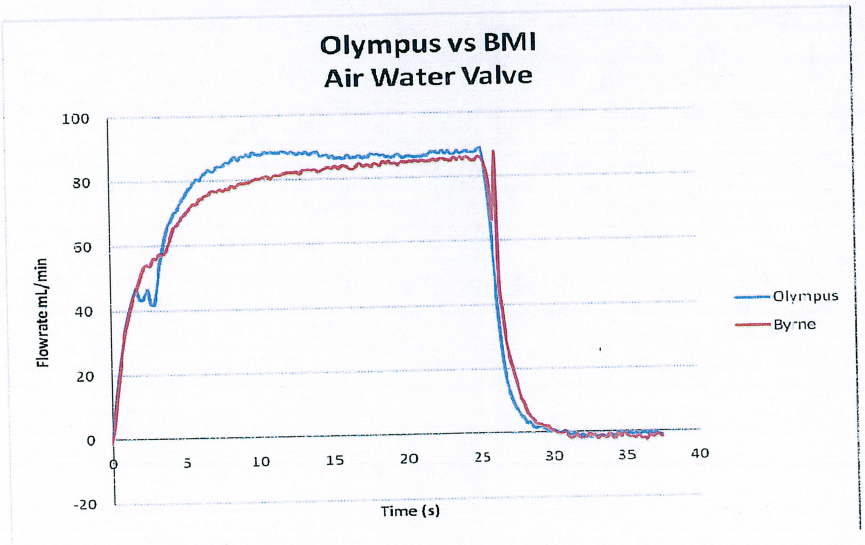
Performance Testing

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



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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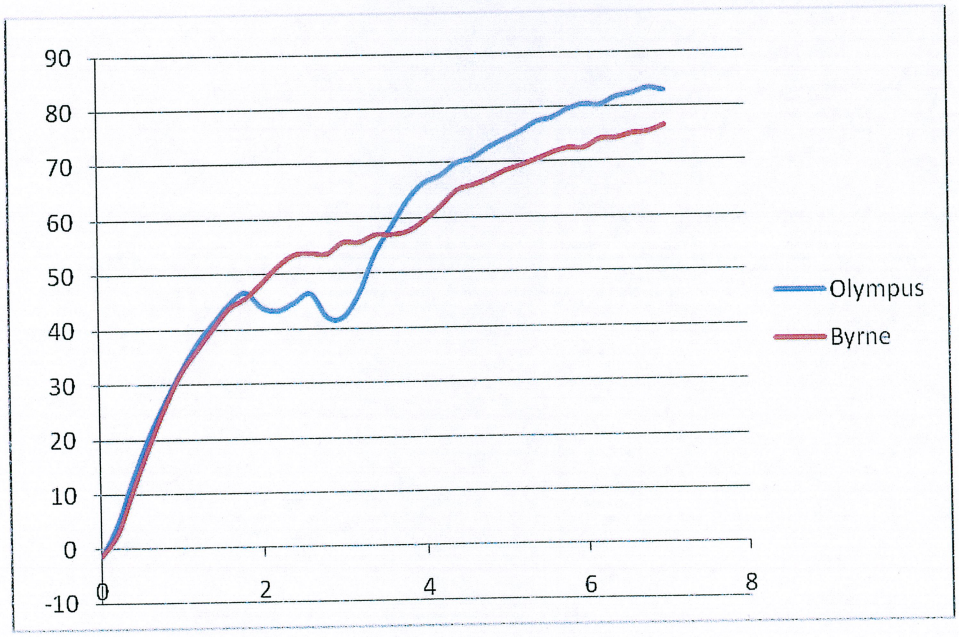
Additionally, measurements from 0 – 7 seconds were analyzed for comparison, the 0-7 second period is significant as this is the typical amount of time the user utilizes for lens cleaning. The following is a graphical depiction of the results:

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Truthful and Accuracy Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Truthful and Accuracy Statement

Pursuant to 21 CFR 807.87(j), I certify that, to the best of my knowledge,

1. The data and other information contained in this premarket notification for the Byrne Medical DEFENDO™ Disposable Air/Water Valve part number 100304, is truthful and accurate, and that,

2. No material fact has been omitted.

J. Willis

John Willis, Director of Regulatory Affairs

8-23-10

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K102409

Date: November 3, 2010
To: The Record
Office: ODE
From: Mary J Cornelius
Division/Branch: DRGUD/ULDB
510(k) Holder: Byrne Medical, Inc
Device Name: Defendo™ Disposable Suction Valve #100304
Common Name:
Contact: John Willis
Phone: 936-521-4240
FAX: 936-521-2381
Email: jrwillis@byrnemedical.com

I. **Purpose and Submission Summary:** The 510(k) holder would like to introduce the Defendo™ Disposable Air/Water Valve #100304 into interstate commerce. This is a new device for Byrne Medical, Inc

II. **Indications for Use:** The DEFENDO™ Disposable Air/Water Valve is intended to be used to control Air/Water function on an endoscope during a GI endoscopic procedure

III. **Administrative Requirements:**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓		
Standards Form #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf	✓		
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf			N/A

IV. **Device Description:** (Section 13) The Byrne Medical DEFENDO™ Disposable air/water valve is a sterile, single use disposable medical device. The DEFENDO™ Disposable air/water valve is a trumpet style valve, which allows the user with the tip of a finger, to control the air/water function on the endoscope by depressing the valve. This completes the circuit in the endoscope

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

By placing the tip of the finger over the hole on top; it allows air to flow through the endoscope allowing insufflation of the colon. By depressing the valve, water is allowed to flow into the endoscope allowing for distal lens cleaning.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?		✓	
Is the device sterile?	✓		
Is the device reusable (not reprocessed single use)?		✓	
Are "cleaning" instructions included for the end user?		✓	

IV. Device Comparison: (Section 14)

Characteristic	Subject: Byrne Medical, Inc	Predicate: Olympus® Evis Exera Colonoscopes K001241
Intended use	The DEFENDO™ Disposable Suction Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure	The Olympus®Disposable Suction Valve is intended to be used to control the air/water function on an Olympus® endoscope during a GI endoscopic procedure
Sterile/Single Use	Yes	No

VI. Labeling: (Section 15) Draft labeling has been provided which includes detailed instructions for use and an appropriate prescription statement as required by CFR 21.807.87 (e).

VII. Sterilization/Shelf Life/Reuse: (Section 16)

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	ETO	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A	
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	EO <20 mg/device ECH <12 mg/device	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	ANSI/AAMI/ISO 11135	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact	10^{-6}	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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skin))		
4. Is it labeled "Pyrogen Free"?		X
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	(b)(4) pouch	
6. Shelf Life (ASTM F1980-2007)	(b)(4) 3 years	

VIII. Materials/Biocompatibility: (Section 17) The DEFENDOTM Disposable Suction valve is an injection molded thermoplastic polycarbonate stem with thermoplastic elastomer over-molded boot and a passivated stainless steel spring. There is no direct patient contact with this device thus, biocompatibility testing was not necessary.

IX. Software: N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety: N/A

XI. Performance Testing – Bench: (Section 20) Bench testing is performed to confirm that the disposable 100304 DEFENDO™ Disposable Air/Water Valve is equivalent to the predicate Olympus® MH-443 Air/Water Valve. Testing included the following:

(b)(4)

- Water flow;

(b)(4)

(b)(4)

XII. Performance Testing – Animal – Clinical: N/A

X. Postmarket Surveillance Information: None

XI. Substantial Equivalence Discussion:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

	Yes	No	
1. Same Indication Statement?	✓		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	✓		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	✓		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

XII. **Recommendation**

Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II,
Product Code: ODC endoscope channel accessory
FDF Colonoscope and accessories

Mary J. Cornelius
Reviewer

11/3/2010
Date

Branch Chief

11/5/10
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Mary J. Cornelius

Subject: 510(k) Number K102409

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓ ✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	✓

Regulation Number	Class*	Product Code
876. 1500	II	ODC

(*If unclassified, see 510(k) Staff)

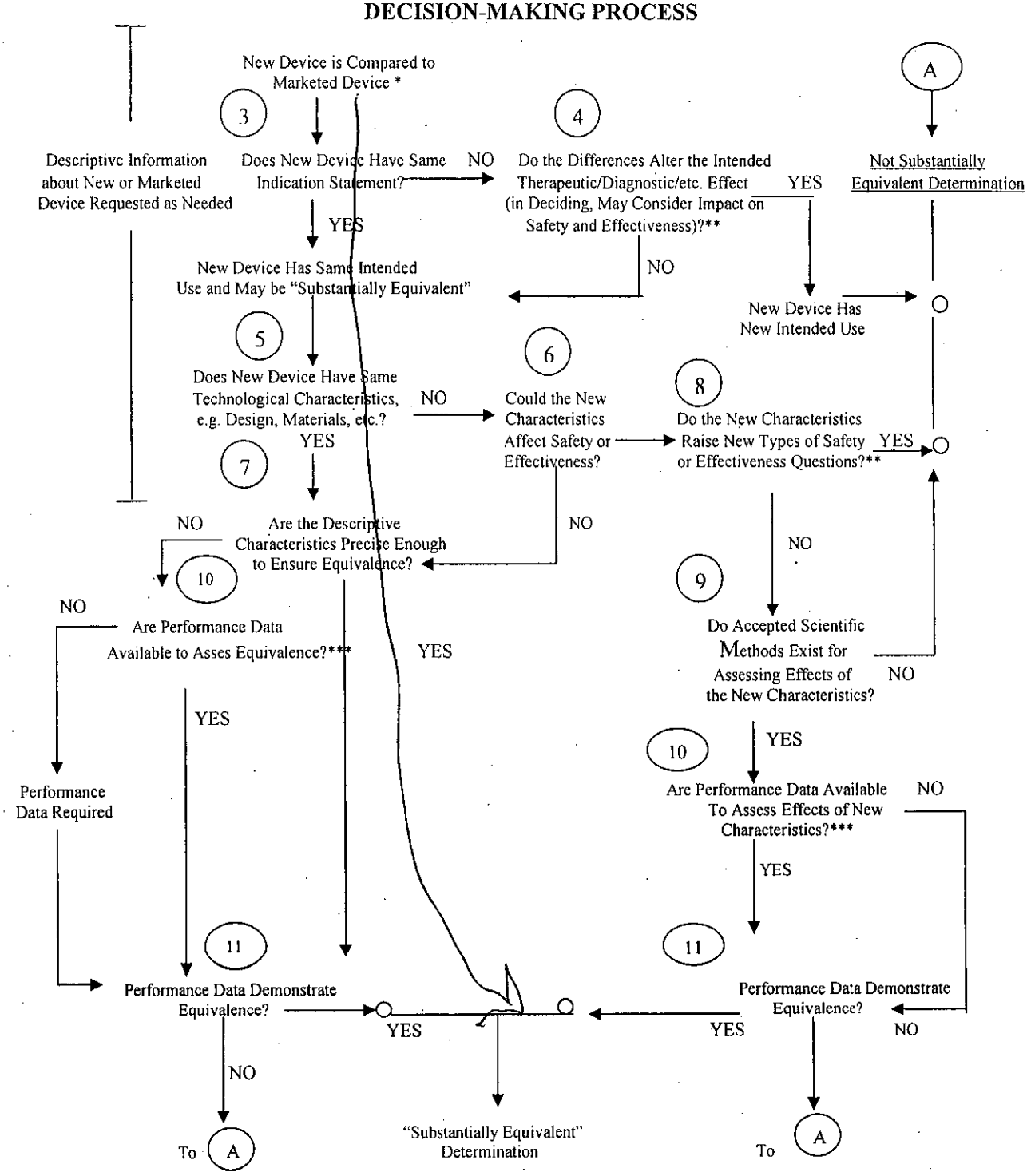
Additional Product Codes: FPF

Review: [signature] (Branch Chief) ULDB (Branch Code) 11/4/10 (Date)

Final Review: [signature] (Division Director) 11/4/10 (Date)

Records processed under FOIA Request # 2016-2207; Released by CDRH on 09-13-20169/13

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118