



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

April 13, 2015

Minimally Invasive Devices Incorporated  
Dr. Trudie L. Seeger, Ph.D.  
Vice President of Regulatory, Quality and Clinical Affairs  
1275 Kinnear Avenue  
Columbus, Ohio 43026

Re: K150705

Trade/Device Name: FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: GCJ  
Dated: March 16, 2015  
Received: March 18, 2015

Dear Dr. Seeger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

  
Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150705

Device Name

FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator

Indications for Use (Describe)

The reusable FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator is an access device indicated for use with a disposable 8.5 — 13mm Cannula Seal manufactured by Applied Medical to provide a passageway for the introduction of endoscopic instruments in general laparoscopic procedures. The access device is compatible with the da Vinci Si Surgical System.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*“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 number.”*



Minimally Invasive Devices Inc  
1275 Kinnear Road  
Columbus, Ohio 43212

## 510(k) Summary (21 CFR §807.92(c))

**510(k) Number:** K150705

**Submitter:** Minimally Invasive Devices, Inc.  
1275 Kinnear Road  
Columbus, Ohio 43212

**Contact:** Trudie L. Seeger, Ph.D.  
V.P., Regulatory/Quality/Clinical Affairs  
Telephone: 614-484-5036  
Fax: 614-484-5034  
E-mail: [tseeger@midsurgical.com](mailto:tseeger@midsurgical.com)

**Date Summary Prepared:** 18 Feb, 2015

**Type of Submission:** Special 510(k)

**Device Trade Name:** FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator

**Common Name:** Cannula and Obturator

**Classification Name:** Laparoscope, General & Plastic Surgery (21 CFR §876.1500)

**Product Code:** GCJ

**Predicate Devices:** FloShield 10mm Endoscopic Cannula and Blunt Obturator  
(K141272)

### Device Description:

The FloShield 10mm Endoscopic Conical Blunt Obturator is a re-usable stainless steel endoscopic instrument delivered non-sterile with the FloShield 10mm Endoscopic Cannula to the hospital where it is cleaned, sterilized (steam / moist heat), and assembled prior to surgery. The FloShield 10mm stainless steel Cannula mates with a disposable Applied Medical 8.5 – 13mm Cannula Seal manufactured and supplied sterile by Applied Medical. The stainless steel Cannula has the ability to connect to a standard male luer fitting, via the female luer that is present on the Cannula. The device will accommodate a standard 8.5mm to 10mm endoscopic instrument (outside diameter). The stainless steel Obturator has a conical blunt style tip which facilitates the insertion of the cannula through an incision site.

**510(k) Summary Page 1 of 3**

**Intended Use/Indications for Use:**

The reusable FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator is an access device indicated for use with a disposable 8.5 – 13mm Cannula Seal manufactured by Applied Medical to provide a passageway for the introduction of endoscopic instruments in general laparoscopic procedures. The access device is compatible with the da Vinci Si Surgical System.

**Comparison to Predicate Devices:**

The FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator has the same design, materials and intended use as the FloShield 10mm Endoscopic Cannula and Blunt Obturator (K141272).

**Technological Characteristics:**

The technological characteristic of the FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator are very similar to the predicate device. The FloShield 10mm Endoscopic Cannula is the same cannula used in the predicate device. The FloShield 10mm Endoscopic Cannula is stainless steel and reusable. The stainless steel Cannula has the ability to connect to a standard male luer fitting, via the female luer that is present on the Cannula. The device will accommodate a standard 8.5mm to 10mm endoscopic instrument (outside diameter) and uses the disposable 8.5 – 13mm Cannula Seal manufactured and supplied sterile by Applied Medical. The stainless steel obturators are functionally identical (i.e., facilitates the insertion of the cannula through an incision site) with the only difference being that the FloShield Conical Blunt Obturator is a Hasson Style conical blunt obturator and the FloShield Blunt Obturator is a full blunt Hasson obturators.

**Performance Testing:**

The performance and functional testing of the FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator included tests to verify its ability to create and maintain a port of entry during simulated laparoscopic surgery, its ability to maintain pneumoperitoneum during the course of surgery and comparable functional characteristics to the predicates (Leak Resistance, Insufflating Flow Rates, Insertion and Removal Force, Snap Retention).

**510(k) Summary Page 2 of 3**



Minimally Invasive Devices Inc  
1275 Kinnear Road  
Columbus, Ohio 43212

Sterilization validation for reusable devices was successfully performed in accordance with ISO 17665: 2006 Sterilization of Healthcare Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices and ANSI/AAMI ST81:2004 (R2010): Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

**Conclusion Drawn from Tests and Analyses:**

The intended use and performance parameters of the FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator are similar or equivalent to the characteristics of the FloShield 10mm Endoscopic Cannula and Blunt Obturator (K141272) as determined in Section 11.0 of this Premarket Notification (510(k)) submission.

**510(k) Summary Page 3 of 3**