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**SAFESTITCH**  
MEDICAL

Premarket Notification Submission 510(k) – Dilator

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## ***Safestitch SMART Dilator 510(k) Summary***

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Company: SafeStitch Medical, LLC. FEB - 6 2009

Contact: Mario Arbesu  
Director, Quality Assurance and Regulatory Affairs  
SafeStitch Medical, LLC.  
4400 Biscayne Boulevard  
Miami, FL 33137  
Phone 305.575.4631  
Fax 305.575.4130

Trade Name: SMART Dilator

Device Type: Esophageal Dilator

Classification Regulation: 876.5365

Class: II

Panel: Gastroenterology/Urology

Product Code: KNQ

Predicate Devices: Savary-Gilliard Dilators (K851955)  
Optical DVS Esophageal Dilator (K031147)

Device Description: The SMART Dilator is a sterile, single use disposable esophageal dilator. The SafeStitch endoscope guide dilator consists of a graduated tube with a center endoscope channel, a tapered tip and a safety handle. The flexible endoscope has a relative rigidity and in combination with the dilator will provide sufficient axial integrity for dilation. The handle provides feedback to indicate how much axial force is being placed on the device and subsequently, the esophagus.

Indications For Use: The SMART Dilator is indicated for dilation of strictures of the esophagus under endoscopic visualization in adults 18 years or older.

Technological Characteristics: The SMART Dilator is similar to the predicate devices in design and operation. The primary differences are the

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handle that provides the user with feedback as to how much force he/she is applying.

Performance Data:

Bench testing was performed to verify the SMART Dilator's performance to internal specifications. In addition, bench testing was also performed to demonstrate that the SMART Dilator is substantially equivalent to both the Savory-Gilliard Dilator and the Optical DVS Esophageal Dilator.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB - 6 2009

Mr. Mario Arbesu  
Director, Quality Assurance and  
Regulatory Affairs  
SafeStitch Medical, LLC  
4400 Biscayne Blvd., Suite 670  
MIAMI FL 33137

Re: K082995  
Trade/Device Name: SMART Dilator  
Regulation Number: 21 CFR §876.5365  
Regulation Name: Esophageal dilator  
Regulatory Class: II  
Product Code: KNQ  
Dated: January 15, 2009  
Received: January 15, 2009

Dear Mr. Arbesu:

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

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

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

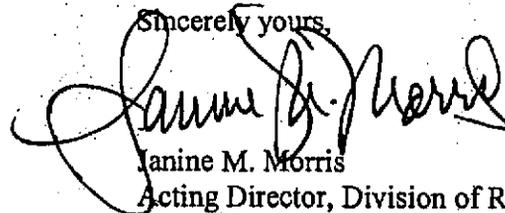
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

|                |                                  |                |
|----------------|----------------------------------|----------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | (240) 276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology)          | (240) 276-0115 |
| 21 CFR 892.xxx | (Radiology)                      | (240) 276-0120 |
| Other          |                                  | (240) 276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry.support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

