

K973803
Dec. 16, 1997

Appendix A 510(k) Summary of Safety and Effectiveness

Statement Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device description The FlexiView CO₂ Blower With Mist is a sterile, single patient use instrument designed to improve visibility at an anastomotic site or other surgical sites by providing an adjustable flow of CO₂ to clear blood or obscuring fluid away and assist in maintaining an open incision or arteriotomy. The optional saline mist helps to prevent desiccation of the graft and surrounding tissue.

The FlexiView CO₂ Blower consists of a handle, a 6" malleable shaft with a nozzle, and connectors for hook up to standard CO₂ source and saline.

Indication for use statement The FlexiView CO₂ Blower is designed to improve visibility at the anastomotic site or other surgical sites where opaque bodily fluid interferes with visualization.

It can be used to assist in anastomoses of tubular structures, such as vessels, nerves, ducts, during procedures such as CABG, MIDCAB, trauma, dialysis access graft procedures, femoral-popliteal, tibial or distal bypasses, and *in situ* bypass.

The FlexiView CO₂ Blower has application in open surgical procedures, such as cardiovascular, peripheral vascular, thoracic, general, gynecological, and urological procedures.

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Appendix A 510(k) Summary of Safety and Effectiveness,
Continued

Technological characteristics

The technological characteristics of the New Device are the same as the Predicate Device.

Performance data

Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. The studies demonstrated acceptable performance to the Predicate Device.

Conclusion

Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the New Device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.

Contact

Lonnie Pace
Project Manager
Regulatory Affairs Department
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Date

October 2, 1997



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20860

DEC 16 1997

Ms. Lorri Chavez
Project Manager, Regulatory Affairs
Ethicon Endo-Surgery, Incorporated
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K973803
Trade Name: Flexview CO2 Blower With Mist
Regulatory Class: II
Product Code: FQH
Dated: October 2, 1997
Received: October 6, 1997

Dear Ms. Chavez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

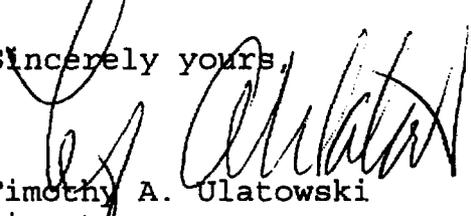
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Appendix B Indications for Use Statement

Statement

Following is the Indications for Use Statement:

510(k) Number: K 973803
Device Name: FlexiView CO₂ Blower With Mist

Indications for Use:

The FlexiView CO₂ Blower is designed to improve visibility at the anastomotic site or other surgical sites where opaque bodily fluid interferes with visualization.

It can be used to assist in anastomoses of tubular structures, such as vessels, nerves, ducts, during procedures such as CABG, MIDCAB, trauma, dialysis access graft procedures, femoral-popliteal, tibial or distal bypasses, and *in situ* bypass.

The FlexiView CO₂ Blower has application in open surgical procedures, such as cardiovascular, peripheral vascular, thoracic, general, gynecological, and urological procedures.

Robert Crockett

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 973803

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