K984101

SEP 3 1999

510(K) SUMMARY

Flexiblade™ -Flexible Laryngoscope

510(k) Number K_____

Applicant's Name:

Arco Medic, Ltd.
Omer Industrial Park
Bldg. 8
Omer 84659, Israel
Tel: 972-7-6499466 Fax: 972-7-6499488

Contact Person:

Shoshana Friedman
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130 Fax: 972-9-7718131

Date Prepared:

November 11, 1998

Trade Name:

Flexiblade™ - Flexible Laryngoscope

Classification Name:

Rigid Laryngoscope

Classification:

Product Code CCW, Class I (exempt)

Predicate Device:

The Flexiblade™ is substantially equivalent to the Welch Allyn Fiber Optic Laryngoscope Model 60813 with Macintosh blade, cleared under K831981, and the Truphatek Fiber Optic Laryngoscope with Macintosh blade, cleared under K883414.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the Flexiblade™ complies with the voluntary standards ASTM F965-85 and ISO 7376-1.

Indication for Use:

The Flexiblade™ is intended for use as an aid for placement of tracheal tube, and for examination and visualization of patient's upper airway.

Device Description:

The Flexiblade™ is a rigid laryngoscope featuring a flexible blade.
The flexibility of the blade is achieved as a result of the motion of a trigger on the laryngoscope handle that its front end is fixed to the front part of the blade and its rear end is free.
This control over the blade flexibility allows the operator performing intubation to place the blade end exactly in the vallecula area elevating the epiglottis with his/her fingers (by gently squeezing the trigger) without changing the device position.

Substantial Equivalence:

Based on a series of performance testing and clinical experience, Arco Medic Ltd. believes that the Flexiblade™ is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 1999

Ms. Shoshana Friedman
General Manager
ArcoMedic Ltd.
c/o Push-Med, Inc.
117 Ahuza Street
Ra'ananna 43373
Israel

Re: K984101
Flexiblade™ Laryngoscope
Regulatory Class: I (one)
Product Code: 73 CCW
Dated: June 5, 1999
Received: June 8, 1999

Dear Ms. Friedman:

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 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). 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 requirements, 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 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K984101

Device Name: Flexiblade™- Flexible Laryngoscope

Indications for Use: The Flexiblade™ - Flexible Laryngoscope is intended for use as an aid for placement of tracheal tube and examination and visualization of patient's upper airway.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____