K060094

510(K) SUMMARY
[as required by 807.92(c)]

Date Submitted:	January 6, 2006
Submitter:	Arcadia Medical Corporation 1450 East American Lane, Suite 1400 Schaumburg, IL 60173 USA Phone: 847-330-4447 Fax: 847-620-2502 E-Mail: mfoote@arcadiamedical.com
Contact Person:	Mr. Mark Foote
Classification Name:	Tube, Tracheal (W/Wo Connector)
Common Device Name:	Tracheal Tube or Endotracheal Tube
Proprietary Name:	Arcadia Medical® Silicone Cuffless Wire Reinforced Endotracheal Tubes with Murphy Eye Arcadia Medical® Silicone Air Cuff Wire Reinforced Endotracheal Tubes with Murphy Eye, Hooded Tip and Above the Cuff Access Port (ACAP)®
Regulatory Class:	II
Classification Number:	BTR
Regulation Number:	868.5730
Panel:	Anesthesiology

Legally Marketed Predicate Devices:

K792035- Fome-Cuf-Wire Reinforced, Aire-Cuf Wire Reinforced Tracheal Tube: Bivona Medical Technologies
K830352- Reinforced Silicone Tracheal Tube: Portex
K954750- Pediatric Wire Reinforced Silicone Endotracheal Tube: Unomedical (Euromedical) Sdn Bhd
K954754- Wire Reinforced Silicone Endotracheal Tube: Unomedical (Euromedical) Sdn Bhd
K991580- ILM Endotracheal Tube: Laryngeal Mask Company, Ltd.

510(K) SUMMARY
[continued]

Device Description:

Arcadia Medical® Silicone Wire Reinforced Endotracheal Tubes are available in Cuffless or Air Cuff styles. All tubes consist of a radiopaque biocompatible wire reinforced silicone shaft and have a standard 15mm connector, depth marks in centimeters and two ring marks behind the cuff for reference in determining the position of the cuff or distal tip in the trachea.

Air Cuff Endotracheal Tubes have a radiopaque hooded tip to ease insertion through the vocal cords. Air Cuff Tubes also have an Above the Cuff Access Port (ACAP)® for removing secretions above the cuff to help prevent aspiration.

Air Cuff Endotracheal Tubes have an inflatable air cuff to seal the trachea. When properly inflated, the air cuff conforms to the shape of the trachea providing an effective seal. The tube has an inflation line with a luer valve and blue pilot balloon to indicate cuff inflation.

Intended Use:

Endotracheal Tubes are indicated for use in providing airway management by oral intubation of the trachea during anesthesia and during ventilator support of respiration. Wire Reinforced Endotracheal Tubes are indicated for use in procedures requiring flexing of the neck or movement of the patient (lateral or prone position).

Technological Characteristics of Device compared to Predicate Devices:

The device is substantially equivalent to the Predicate devices in all aspects except the following;

The Air Cuff Model has a unique molded tip and a suction port above the cuff to remove secretions.

Performance Data:

Performance Data for the device is shown in Section 11: Performance Standards

Performance Data indicates that the device is substantially equivalent in performance to the predicate device.

Conclusion:

Comparison of the device to the predicate devices supports the conclusion that the device is substantially equivalent in safety and effectiveness and in its intended use to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2006

Mr. Mark Foote
President
Arcadia Medical Corporation
1450 East American Lane, Suite 1400
Schaumburg, Illinois 60173

Re: K060094
Trade/Device Name: Arcadia Medical® Silicone Wire Reinforced Endotracheal Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: April 29, 2006
Received: May 3, 2006

Dear Mr. Foote:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060094

Device Name: Arcadia Medical® Silicone Wire Reinforced Endotracheal Tubes

Indications for Use:

Endotracheal Tubes are indicated for use in providing airway management by oral intubation of the trachea during anesthesia and during ventilator support of respiration. Wire Reinforced Endotracheal Tubes are indicated for use in procedures requiring flexing of the neck or movement of the patient (lateral or prone position).

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 Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K060094