K03553

NOV 1 8 2003

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

Submitter of 510(k):

Arcadia Medical Corporation
1450 East American Lane, Suite 1400
Schaumburg, IL 60173
USA

Phone: 847-330-4447
Fax: 847-438-4693

Contact Person: Mr. James Mondschean

Date of Summary: May 15, 2003

Trade Name: Silicone Foam Cuff Tracheostomy Tubes, Silicone Cuffless Neonatal and Pediatric Tracheostomy Tubes, Silicone Cuffless Adult Tracheostomy Tubes, Silicone Air Cuff and Air Cuff Adjustable Neck Flange Tracheostomy Tubes

Classification Name: TUBE, TRACHEOSTOMY (W/WO CONNECTOR)

Predicate Device: Bivona Medical Technologies – Fome-Cuf and Aire Cuf

Tracheostomy Tubes	K862267
Aire Cuf Adjustable	K894614
Pediatric Trach Tube	K912469

Intended Use:

Tracheostomy tubes are intended for use in providing direct tracheal access for airway management.

Tracheostomy Tube Predi ء Device Comparison Chart

Product Type: Arcadia Medical Adult Cuffless Tracheostomy Tubes

Intended Use: Direct Tracheal Access for Airway Management such as Anesthesia, Artificial Ventilation or Respiratory Therapy

Characteristic	Arcadia Medical	Bivona Medical (Predicate Device)
Size Range: 6.0mm, 7.0mm, 8.0mm, 9.0mm, 9.5mm (5 Sizes)	Yes	Yes- plus 5.0mm (6 sizes)
Length: 6.0=51mm, 7.0=67mm, 8.0=78mm, 9.0=91mm, 9.5=95mm	Yes	5.0=60mm, 6.0=70mm, 7.0=80mm 8.0=88mm, 9.0=98mm, 9.5=98mm
Neck Flange with OD/ID, Name & Model Type	Yes	Yes
Material: Silicone	Yes	Yes
Radiopaque	Yes	Yes
Color: White	Yes	Yes
15mm Connector	Yes	Yes
Cuff Style: Cuffless	Yes	Yes
Obturator	Yes	Yes
Packaging: PETG Tray with Tyvek Lid	Yes	Yes
Packaged with Accessories: Twill Tape and Disconnect Wedge	Yes	Yes
Sterilization Method: ETO	Yes	Yes
Label contains the following information: Product Name, product style (Cuffless), size, Part Number, ID, OD, Length, Lot Number, Manufacturer's Name, Quantity, Sterile-ETO, Expiration Date	Yes	Yes
Complies with ASTM F 1666-95: Standard Specification for Adult Tracheostomy Tubes	Yes	Yes

Tracheostomy Tube Pred. .e Device Comparison Chart

Product Type: Arcadia Medical Pediatric Cuffless Tracheostomy Tubes

Intended Use: Direct Tracheal Access for Airway Management such as Anesthesia, Artificial Ventilation or Respiratory Therapy

Characteristic	Arcadia Medical	Bivona Medical (Predicate Device)
Size Range: 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm (7 Sizes)	Yes	Yes
Length: 2.5=38mm, 3.0=39mm, 3.5=40mm, 4.0=41mm, 4.5=42mm, 5.0=44mm, 5.5=46mm	Yes	Yes
Neck Flange with OD/ID, Name & Model Type	Yes	Yes
Material: Silicone	Yes	Yes
Radiopaque	Yes	Yes
Wire Reinforced	Yes	Yes
Color: White	Yes	Yes
15mm Connector	Yes	Yes
Cuff Style: Cuffless	Yes	Yes
Obturator	Yes	Yes
Packaging: PETG Tray with Tyvek Lid	Yes	Yes
Packaged with Accessories: Twill Tape and Disconnect Wedge	Yes	Yes
Sterilization Method: ETO	Yes	Yes
Label contains the following information: Product Name, product style (Cuffless), size, Part Number, ID, OD, Length, Lot Number, Manufacturer's Name, Quantity, Sterile-ETO, Expiration Date	Yes	Yes
Complies with ASTM F 1627-95: Standard Specification for Pediatric Tracheostomy Tubes	Yes	Yes

Tracheostomy Tube Pred a Device Comparison Chart

Product Type: Arcadia Medical Neonatal Cuffless Tracheostomy Tubes

Intended Use: Direct Tracheal Access for Airway Management such as Anesthesia, Artificial Ventilation or Respiratory Therapy

Characteristic	Arcadia Medical	Bivona Medical (Predicate Device)
Size Range: 2.5mm, 3.0mm, 3.5mm, 4.0mm, (4 Sizes)	Yes	Yes
Length: 2.5=30mm, 3.0=32mm, 3.5=34mm, 4.0=36mm	Yes	Yes
Neck Flange with OD/ID, Name & Model Type	Yes	Yes
Material: Silicone	Yes	Yes
Radiopaque	Yes	Yes
Wire Reinforced	Yes	Yes
Color: White	Yes	Yes
15mm Connector	Yes	Yes
Cuff Style: Cuffless	Yes	Yes
Obturator	Yes	Yes
Packaging: PETG Tray with Tyvek Lid	Yes	Yes
Packaged with Accessories: Twill Tape and Disconnect Wedge	Yes	Yes
Sterilization Method: ETO	Yes	Yes
Label contains the following information: Product Name, product style (Cuffless), size, Part Number, ID, OD, Length, Lot Number, Manufacturer's Name, Quantity, Sterile-ETO, Expiration Date	Yes	Yes
Complies with ASTM F 1627-95: Standard Specification for Pediatric Tracheostomy Tubes	Yes	Yes

Tracheostomy Tube Predi[illegible]e Device Comparison Chart

Product Type: Arcadia Medical Adult Foam Cuff Tracheostomy Tubes

Intended Use: Direct Tracheal Access for Airway Management such as Anesthesia, Artificial Ventilation or Respiratory Therapy

Characteristic	Arcadia Medical	Bivona Medical (Predicate Device)
Size Range: 6.0mm, 7.0mm, 8.0mm, 9.0mm, 9.5mm (5 Sizes)	Yes	Yes- plus 5.0mm (6 sizes)
Length: 6.0=51mm, 7.0=67mm, 8.0=78mm, 9.0=91mm, 9.5=95mm	Yes	5.0=60mm, 6.0=70mm, 7.0=80mm 8.0=88mm, 9.0=98mm, 9.5=98mm
Neck Flange with OD/ID, Name & Model Type	Yes	Yes
Material: Silicone	Yes	Yes
Radiopaque	Yes	Yes
Color: White	Yes	Yes
15mm Connector	Yes	Yes
Cuff Style: Foam Cuff with Pilot Port and attached plug	Yes	Yes
Obturator	Yes	Yes
Packaging: PETG Tray with Tyvek Lid	Yes	Yes
Packaged with Accessories: Twill Tape and Disconnect Wedge	Yes	Yes
Sterilization Method: ETO	Yes	Yes
Label contains the following information: Product Name, product style (Foam Cuff), size, Part Number, ID, OD, Length, Lot Number, Manufacturer's Name, Quantity, Sterile-ETO, Expiration Date	Yes	Yes
Complies with ASTM F 1666-95: Standard Specification for Adult Tracheostomy Tubes	Yes	Yes

Tracheostomy Tube Pred e Device Comparison Chart

Product Type: Arcadia Medical Adult Air Cuff Tracheostomy Tubes

Intended Use: Direct Tracheal Access for Airway Management such as Anesthesia, Artificial Ventilation or Respiratory Therapy

Characteristic	Arcadia Medical	Bivona Medical (Predicate Device)
Size Range: 6.0mm, 7.0mm, 8.0mm, 9.0mm, 9.5mm (5 Sizes)	Yes	Yes- plus 5.0mm (6 sizes)
Length: 6.0=51mm, 7.0=67mm, 8.0=78mm, 9.0=91mm, 9.5=95mm	Yes	5.0=60mm, 6.0=70mm, 7.0=80mm 8.0=88mm, 9.0=98mm, 9.5=98mm
Neck Flange with OD/ID, Name & Model Type	Yes	Yes
Material: Silicone	Yes	Yes
Radiopaque	Yes	Yes
Color: White	Yes	Yes
15mm Connector	Yes	Yes
Cuff Style: Air Cuff with Pilot Balloon, Inflation Valve and Inflation Line	Yes	Yes
Obturator	Yes	Yes
Packaging: PETG Tray with Tyvek Lid	Yes	Yes
Packaged with Accessories: Twill Tape and Disconnect Wedge	Yes	Yes
Sterilization Method: ETO	Yes	Yes
Label contains the following information: Product Name, product style (Air Cuff), size, Part Number, ID, OD, Length, Lot Number, Manufacturer's Name, Quantity, Sterile-ETO, Expiration Date	Yes	Yes
Complies with ASTM F 1666-95: Standard Specification for Adult Tracheostomy Tubes	Yes	Yes

Tracheostomy Tube Pred e Device Comparison Chart

Product Type: Arcadia Medical Adult Air Cuff Adjustable Neck Flange Tracheostomy Tubes

Intended Use: Direct Tracheal Access for Airway Management such as Anesthesia, Artificial Ventilation or Respiratory Therapy

Characteristic	Arcadia Medical	Bivona Medical (Predicate Device)
Size Range: 6.0mm, 7.0mm, 8.0mm, 9.0mm (4 Sizes)	Yes	Yes
Usable Length: 6.0=110mm, 7.0=120mm, 8.0=130mm, 9.0=140mm	Yes	Yes
Adjustable Neck Flange with OD/ID, Name & Model Type	Yes	Yes
Material: Silicone	Yes	Yes
Radiopaque	Yes	Yes
Wire Reinforced	Yes	Yes
Color: Clear	Yes	Yes
15mm Connector	Yes	Yes
Cuff Style: Air Cuff with Pilot Balloon, Inflation Valve and Inflation Line	Yes	Yes
Above the Cuff Access Port for Suctioning and Vocalization	Yes	Not Available on this Model (Available on other Bivona Models)
Introducer/Obturator	Yes	Yes
Packaging: Tyvek Pouch	Yes	Yes
Packaged with Accessories: Twill Tape and Disconnect Wedge	Yes	Yes
Sterilization Method: ETO	Yes	Yes
Label contains the following information: Product Name, product style (Air Cuff), size, Part Number, ID, OD, Length, Lot Number, Manufacturer's Name, Quantity, Sterile-ETO, Expiration Date	Yes	Yes
Complies with ASTM F 1666-95: Standard Specification for Adult Tracheostomy Tubes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2003

Arcardia Medical Corporation
c/o Mr. Arthur Ward
RMS
962 Allegro Lane
Apollo Beach, FL 33572

Re: K031553
Trade/Device Name: Silicone Tracheostomy Tubes
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tubes (W/Wo Connector)
Regulatory Class: II
Product Code: BTO
Dated: September 26, 2003
Received: October 2, 2003

Dear Mr. Ward:

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 (301) 594-4646. 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/dsma/dsmamain.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

510(k) Number (if known): K031553

Device Name: Arcadia Medical Tracheostomy tubes

Indications For Use:

Tracheostomy tubes are intended for use in providing direct tracheal access for airway management.

(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: K031553

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)