

10073702

510(k) Summary
for **JUN 26 2008**
Phoneris™ Inner Cannulae and
Phoneris™ Aero-Flex™ Ventilator Circuit Connector

1. SPONSOR

Lazarus Medical
10805 S. Marion Ave.
Tulsa, OK 74137

Contact Person: Aaron Dirks
Telephone: 918-409-5590

Date Prepared: December 28, 2007

2. DEVICE NAME

Proprietary Name: Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector
Common/Usual Name: Tracheostomy tube accessory
Classification Name: Tracheostomy tube and tube cuff

3. PREDICATE DEVICE

- Shiley Disposable Cannula Tracheostomy Tube (K811447)

4. INTENDED USE

The Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector is indicated for airway maintenance of tracheostomised patients. The single use, disposable device is an accessory to a tracheostomy tube, serving as an interlocking, detachable coupling between the ventilator circuit and inner cannula of the tracheostomy tube. The Phoneris™ Inner Cannulae component is designed to replace the disposable inner cannulae component of the Shiley Disposable Cannula Tracheostomy Tube.

5. DEVICE DESCRIPTION

The proposed Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector device consists of two components, the sterile Phoneris™ Inner Cannulae (Inner Cannulae) and the non-sterile Aero-Flex™ Ventilator Circuit Connector (Aero-Flex™). The Inner Cannulae is designed to replace the disposable inner cannulae component of the Shiley Disposable Cannula Tracheostomy Tube that was cleared for market in K811447.

The Inner Cannulae consists of a snap-lock connector with an integral tube. The Inner Cannulae is inserted into the outer cannula of the Shiley Disposable Cannula Tracheostomy Tube and snap-locked into place at the proximal end of the snap-lock connector component of the Inner Cannulae. The distal end of the Inner Cannulae snap-lock connector attaches to the proximal end of the Aero-Flex™ in an interlocking fashion. The free end of the Aero-Flex™ in turn attaches to the leading connector of the ventilator tube via a standard tapered connection that complies with ISO 5356-1:2004 “Anaesthetic and Respiratory Equipment – Conical connectors – Part 1: Cones and Sockets”.

The proposed Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector device provides a positive, detachable connection between the Shiley Disposable Cannula Tracheostomy Tube and ventilator circuit. This interlocking coupling design relieves patient discomfort associated with the frequent necessary disconnections and reconnections of the outer cannula from the ventilator circuit for maintenance purposes, and reduces the opportunity for inadvertent detachment of the tracheostomy tube from the connected respiratory delivery system. This decreases patient discomfort by relieving the suffocation sensation a ventilator dependent patient may experience with disconnection. It also decreases valuable nursing and respiratory therapists’ time needed to repeatedly reconnect the patient to the ventilator as well as decreasing the potentially catastrophic effects of ventilator disconnects.

The proposed Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector device is not supplied with an outer cannula. Neither component of the proposed device is indicated for insertion into the patient’s windpipe.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The operational principles and overall design of the proposed Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector is similar to that of the predicate Shiley Disposable Cannula Tracheostomy Tube (K811447). The major difference between the proposed and predicate devices lies in the type of connection made between the tracheostomy tube and the ventilator circuit. For the predicate device, the connection between the inner cannula and the airway connector is a standard tapered connection. In the proposed device, the Inner Cannulae component connects to the Aero-Flex™ component via an interlocking connection. The distal end of the Aero-Flex™ component in turn connects to the ventilator circuit tubing via a standard tapered connection.

Testing was conducted to validate the sterilization of the Inner Cannulae component. Biocompatibility testing confirmed the biological safety of the proposed Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector for use as a tracheostomy tube accessory. Additional testing was initiated to support the claimed shelf life. The data from these tests confirm that the differences between the proposed and predicate devices are minor and raise no new issues of safety and effectiveness. A comparison of the intended use and technological characteristics of the proposed and predicate devices is provided in Table 5-1.

Table 5-1. Comparison Table for Determination of Substantial Equivalence

Item for Comparison	Phoneris™ Inner Cannulae and Phoneris™ Aero-Flex™ Ventilator Circuit Connector Lazarus Medical (proposed)	Shiley Disposable Cannula Tracheostomy Tube Shiley, Inc. K811447
Intended Use	Airway maintenance of tracheostomised patients	
Components	<ul style="list-style-type: none"> • Inner Cannulae* • Aero-Flex Ventilator Circuit Connector 	<ul style="list-style-type: none"> • Inner cannula • Outer cannula
Connection between tracheostomy tube and ventilator circuit	<ul style="list-style-type: none"> • Interlocking between Inner Cannula and Aero-Flex Ventilator Circuit Connector • Tapered between Aero-Flex Ventilator Circuit Connector and ventilator circuit 	Tapered
Dimensions	<i>Inner Cannulae</i> <ul style="list-style-type: none"> • ID: 5.0 – 8.9 mm • OD: 7.5 – 11.0 mm • Length: 74.7-94.3 mm <i>Aero-Flex†</i> <ul style="list-style-type: none"> • ID: 9.1 mm (at narrowest point) • Length: 73.101 mm 	<ul style="list-style-type: none"> • ID: 5.0 – 8.9 mm • OD: 9.4 – 13.8 mm • Length: 62.0 – 79.0 mm
Materials	<i>Inner Cannulae</i> <ul style="list-style-type: none"> • Tube: PVC • Body and sliding lock: PP <i>Aero-Flex Ventilator Circuit Connector</i> <ul style="list-style-type: none"> • Flange: Cyrolite • Tube: HDPE • Body: PP 	Polymer
Sterility status	<ul style="list-style-type: none"> • Inner Cannulae: sterile • Aero-Flex Ventilator Circuit Connector: non-sterile 	Sterile

*Replaces disposable inner cannulae component of Shiley Disposable Cannula Tracheostomy Tube

†One size Aero-Flex™ is compatible with all sizes of Inner Cannulae

PVC = polyvinyl chloride

PP = polypropylene

HDPE = high density polyethylene



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2008

Lazarus Medical LLC
C/O Dr. Cynthia J. M. Nolte
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K073702

Trade/Device Name: Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™
Ventilator Circuit Connector

Regulation Number: 21 CFR 868.5800

Regulation Name: Tracheostomy Tube and Tube Cuff

Regulatory Class: II

Product Code: BTO

Dated: June 16, 2008

Received: June 18, 2008

Dear Dr. Nolte:

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.

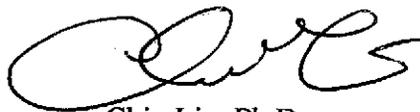
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known):

Device Name: Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector

Indications for Use:

The Phoneris™ Inner Cannulae with Phoneris™ Aero-Flex™ Ventilator Circuit Connector is indicated for airway maintenance of tracheostomised patients. The single use, disposable device is an accessory to a tracheostomy tube, serving as an interlocking, detachable, coupling between the ventilator circuit and tracheostomy tube. The Phoneris™ Inner Cannulae component is designed to replace the disposable inner cannulae component of the Shiley Disposable Cannula Tracheostomy Tube.

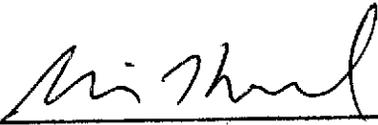
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 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: K073702