K090777

Section V–510(k) Summary

AUG 0 4 2009

5.1. Device Information

Category	*Comments*
Sponsor:	Company: EZC Medical, LLC Address: The Presidio 16A Funston Avenue San Francisco, Ca, 94129, USA Tel: (415) 561-2550
Correspondence Contact Information:	Pavan Sethi, Ph.D. Vice President, Regulatory, Quality & Scientific Affairs Tel: (408) 513-7529 Pavan@ezcmedical.com
Device Common Name:	Stylet / Videoscope
Device Classification and Code:	Class II, BTR
Device Classification Name:	Tracheal Tube (Accessory)
Device Proprietary Name:	IntubaidFlex™

5.2. Predicate Device Information

Predicate Device:	ETView Tracheoscopic Ventilation Tube (TVT™)
Predicate Device Manufacturer:	ETView Ltd
Predicate Device Common Name	Tracheal Tube
Predicate Device Classification and Code:	Class II, BTR
Predicate Device Classification:	21CFR868.5730

5.3. Date Summary Prepared

Date Submitted: March 20, 2009

5.4. Description of Device:

The IntubaidFlex™ is a simple, disposable, single-patient use, sterile, handheld, portable stylet with a built in camera, that fits within an Endotracheal tube (ETT) directly or through an Intubating Laryngeal Mask Airway(LMA) and provides for video-assisted visualization of the laryngeal inlet. The IntubaidFlex™ can plug into any TV monitor, hand held monitor or PC (via USB) for live video visualization.

5.5. Intended Use

The IntubaidFlex™ is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly or through an Intubating Laryngeal Mask Airway (LMA) during non difficult and difficult intubation procedures. The IntubaidFlex achieves its purpose by providing the user with a visual confirmation of where the

tip of the device is in the human anatomy. The flexible tip of the IntubaidFlex allows the user to guide the ETT in the desired direction.

5.6. Comparison to Predicate Device:

The EZC Medical's IntubaidFlex™ is substantially equivalent to ETView Tracheoscopic Ventilation Tube (TVT™) in intended use and operation (K082420).

Both the devices are endoscopic, and transmit images through a video camera to a video monitor and use a light source for illumination. Both the devices are disposable, single-patient use, sterile, have an embedded video camera, an embedded light source, and an integrated cable which connects to the video monitor.

The devices are different in design. The IntubaidFlex™ is an accessory to the ETT, where as TVT™ is an Endotracheal Tube by itself. The IntubaidFlex™ has an articulation capability, which TVT™ does not have.

However, these differences do not impact the intended use or optical performance of the IntubaidFlex. The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

EZC Medical concludes that the devices are substantially equivalent.

5.7. Summary of Supporting Data:

Biocompatibility data demonstrates that the device is in compliance with *ISO 10993*.

Electrical Safety and Electromagnetic Compatibility data demonstrates that the device is in compliance with *IEC 60601-1* and *IEC 60601-1-2*.

Bench testing has demonstrated that the device is in compliance with *ISO 8600-3* and *ISO 8600-5*. In addition the bench testing included the Tensile Strength test, Drop test and Fatigue test. The Tensile Strength Test demonstrated that joints can withstand a 5.0 lb tensile load, the Drop Test demonstrated that the device can withstand a 36 inch fall and the Fatigue test demonstrated that the plunger can withstand multiple actuations without affecting the image functionality of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 0 4 2009

Ms. Pavan Sethi
Vice President Regulatory, Quality & Scientific Affairs
EZC Medical, L.L.C.
16 A Funston Avenue
San Francisco, California 94129

Re: K090777
Trade/Device Name: EZC Medical, LLC, IntubaidFlex™
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: July 27, 2009
Received: July 29, 2009

Dear Ms. Sethi:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A. .
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section IV–Indications for Use Statement

510(k) Number: K090777

Device Name: EZC Medical, LLC, IntubaidFlex™

Indications for Use:

The IntubaidFlex™ is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly or through an Intubating Laryngeal Mask Airway (LMA) during non difficult and difficult intubation procedures. The IntubaidFlex achieves its purpose by providing the user with a visual confirmation of where the tip of the device is in the human anatomy. The flexible tip of the IntubaidFlex allows the user to guide the ETT in the desired direction.

Prescription Use ___X___ (Per 21 CFR §801 subpart D) OR Over-The-Counter Use_____ (Per 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

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