JAN - 7 2005

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

K041917

A. General Information

1.	*Submitter's Name:*	PlasiaTEK, LLC
2.	*Address:*	10560 Wayzata Blvd. Minneapolis, MN 55305
3.	*Telephone:*	952-593-9960
4.	*Contact Person:*	Paul Pesek
5.	*Date Prepared:*	July 15, 2004
6.	*Registration Number:*	Pending

B. Device

1.	*Name:*	PlasiaTEK™ Actuator
2.	*Trade Name:*	PlasiaTEK Actuator
3.	*Common Name:*	Actuator
4.	*Classification Name:*	Tracheal Tube (w/wo connector)
5.	*Product Code:*	BTR
6.	*Class:*	II
7.	*Regulation Number:*	868.5730

C. Identification of Legally Marketed Devices

1.	*Name:*	PosiTube Esophageal Intubation Detection Device
2.	*K Number:*	K000045
3.	*Date Cleared:*	3/15/2000

D. Description of the Device

The PlasiaTEK™ Actuator Device is a small, non-invasive, battery operated vibrating accessory with an on/off switch that is attached to the ventilation circuit connector on the proximal end of an endotracheal tube. The PlasiaTEK Actuator is used in combination with a previously cleared-to-market endotracheal tube and standard Doppler ultrasound system to locate the endotracheal tube within the trachea. When turned on, the Actuator slightly vibrates the tube. An imaging Doppler ultrasound system can detect the endotracheal tube position because of the gentle small motion caused by the PlasiaTEK Actuator.

E. Intended Use Statement

The PlasiaTEK Actuator is a non-invasive accessory to support verification of placement of an endotracheal tube within the trachea using standard Doppler ultrasound imaging.

F. Intended Use and Technological Characteristics Summary

The PlasiaTEK Actuator is substantially equivalent to the PosiTube Esophageal Intubation Detection Device in terms of Intended Use.

Technologically, both devices are similar since they are non-invasive, applied to the proximal connector end of the endotracheal tube and must be activated to work.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2005

Mr. Paul Pesek
President
PlasiaTEK, LLC
10560 Wayzata Boulevard
Minneapolis, Minnesota 55305

Re: K041917
Trade/Device Name: PlasiaTEK™ Actuator
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: December 23, 2004
Received: December 29, 2004

Dear Mr. Pesek:

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) 594-0120. 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

Indications for Use

510(k) Number (if known): K041917

Device Name: PlasiaTEK™ Actuator

Indications For Use:

The PlasiaTEK Actuator is a non-invasive accessory to support verification of placement of an endotracheal tube within the trachea using Doppler ultrasound imaging.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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: K041917