MAY - 4 2004

K033189

Section #7

PREMARKET SUMMARY
(As Required By 21 CFR 807.93)

Contact person: Tom McGrail Alternate contact: Charles Burt
King Systems Corporation
Establishment Registration Number: 1824226
15011 Herriman Boulevard
Noblesville, IN 46060
Telephone: 317 776-6823

General Information

Proprietary or Trade Name: KING LTS™
KLT 303 Size 3 Small adult oropharyngeal airway
KLT 304 Size 4 Medium adult oropharyngeal airway
KLT 305 Size 5 Large adult oropharyngeal airway
Common/Usual Name: LTS
Classification Name: Oropharyngeal airway; CAE (21 CFR 868.5110).
Classification: Class I (New fundamental scientific technology exceeds limitations of exemptions found in 21 CFR 868.9.)
Classification Panel: Anesthesiology Review Committee
Reason for Premarket Notification: Product manufactured in Germany is new to U.S. market.

The intended device is similar in intended use, material, safety and effectiveness in similar applications to: King Systems Corporation KLT Oropharyngeal Airway (510(k) **#K021634**). The intended use and indications of the modified device, as described in its labeling, are the same as those for the unmodified predicate device. The modification has not altered the fundamental technology of the predicate device.

The device is to be distributed by King Systems as non-sterile, clean. Sterilization information is provided as part of the instructions for use. Manufacturer's tests have shown the device to successfully withstand fifty or more cleaning and autoclave sterilization cycles.

The following voluntary standards are utilized in whole or in part: ISO 5356-1/1996-12-15, Anesthetic and Respiratory Equipment-conical Connectors, Part 1- cones and sockets; ASTM F1242-96 Standard Specifications for Cuffed and Uncuffed Tracheal Tubes.

The materials in the device are identical to materials used in the identified predicate device.

Comparison of the KING LT™ to the legally marketed predicate device:

Characteristic	KING LTS™	KING LT™
510(k) Number	**TBD (this submission)**	**K021634**
Intended Use Ventilation during anesthesia during procedures of short duration. An oropharyngeal airway is a device inserted through the mouth to provide a patent airway.	**Yes**	**Yes**
Design Tube with two attached, inflatable balloons	**Yes**	**Yes**
Ventilation openings between the balloons	**Yes**	**Yes**
Can be sterilized in an autoclave	**Yes**	**Yes**
Proximal ISO Standard 15mm connector for attachment to breathing circuit	**Yes**	**Yes**
Medical grade polymers or approved materials for all components in contact with the anesthesia gas stream	**Identical to materials in predicate device**	**Yes**
Summary of Features Connected to a Breathing Circuit	**Yes**	**Yes**
Internal Volume (dead space) (ml) *	**8.7**	**9.0**
Resistance cmH_2O @ 30 L/min*	**1.6**	**1.3**
Weight (gm) *	**51.3**	**32.2**
Prescription use only?	**Yes**	**Yes**
Inserted blindly?	**Yes**	**Yes**
Enters the trachea?	**No**	**No**
Seals the esophagus?	**Yes**	**Yes**
Cuffs are inflated with one inflation port?	**Yes**	**Yes**
Instructions that patient should have fasted before using the product?	**Yes**	**Yes**
Latex free product	**Yes**	**Yes**
Product classification	**CAE**	**CAE**

*Size 4 for both the KING LTS™ and the KING LT™ is used for this comparison of weight, dead space, and resistance. Size 4 is the middle size for both product lines, and variations in these criteria in the other sizes are expected to be proportionally, approximately equal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2004

Tom McGrail
Director, R & D
King Systems Corporation
15011 Herriman Blvd.
Noblesville, IN 46060

Re: K033189
Trade/Device Name: King LTS Reusable Oropharyngeal Airway with Drain/Suction
Regulation Number: 21 CFR 868.5110
Regulation Name:
Regulatory Class: I
Product Code: CAE
Dated: April 2, 2004
Received: April 5, 2004

Dear Mr. McGrail:

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.

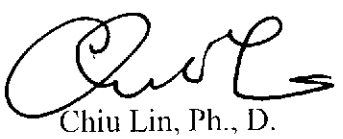
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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

Indications for Use

510(k) number: K033189

Device name:

KLTS 303 Size 3	Small adult KING LTS oropharyngeal airway
KLTS 304 Size 4	Medium adult KING LTS oropharyngeal airway
KLTS 305 Size 5	Large adult KING LTS oropharyngeal airway

Indications for Use:

The KING LTS is intended for use in adult patients (in excess of 25 kg) for controlled ventilation during anesthesia for procedures that are short in duration and when the patient is considered to have a low risk of aspiration of stomach contents.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (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: K033189