K033186

APR 1 4 2004

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 LT-D
KLT 203 Size 3 Small adult disposable oropharyngeal airway
KLT 204 Size 4 Medium adult disposable oropharyngeal airway
KLT 205 Size 5 Large adult disposable oropharyngeal airway
Common/Usual Name: LT-D
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: A disposable version of an existing reusable device is intended for introduction into the US market.

The KING LT-D is similar in intended use, material, safety and effectiveness 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 sterile, for single patient use.

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; EN30993/ISO 10993, Biocompatibility Evaluation of Medical Devices.

The materials in the device are identical to materials used in other medical devices that have the same level of patient contact.

This device is not software driven. Software validation and verification is not applicable.

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

Characteristic	KING LT-D	KING LT™
510(k) Number	**TBD (this submission)**	**K002458**
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**
Sterile device indicated for single patient use.	**Yes**	**No**
ISO Standard 15 mm proximal connector for attachment to breathing circuit	**Yes**	**Yes**
Medical grade polymers or approved materials for all components in contact with the anesthesia gas stream.	**Yes**	**Yes**
Summary of Features Connected to a Breathing Circuit	**Yes**	**Yes**
11.5 mm internal diameter	**Yes**	**Yes**
Weight (gm)	**32.1**	**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**

Device Description

Each device is constructed of medical grade elastomeric and thermoplastic materials. All fittings conform to ISO 5356-1/1996; Anesthetic and Respiratory Equipment - Conical Connectors; Part 1 Cones and Sockets. The device incorporates the following components or features:

- Bi-directional gas flow through a ventilation channel.
- Inflatable bladders to assist in maintenance of placement and in sealing the airway from the stomach and from the atmosphere
- Indicators for proper placement permanently printed on the tube
- A rigid plastic connector complying with ISO standards for the 15mm connection to the patient end of a breathing circuit.

King Systems Corporation (establishment registration number 1824226) will be the exclusive U.S. distributor for this line of oropharyngeal airways. The product is manufactured in Malaysia.

Each device is distributed as an individually packaged sterile device for single patient use.

As required by the risk analysis performed for the KING LT-D, the designated individual(s) performed all verification and validation activities and the results of the activities demonstrated that the predetermined acceptance criteria were met. King Systems Corporation is in conformance with the design control procedure requirements as specified in 21 CFR 820.30, and the records are available for review.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

Mr. Tom McGrail
Director, Research & Development
King System, Corporation
15011 Herriman Boulevard
Noblesville, Indiana 46060

Re: K033186
Trade/Device Name: KING LT –D Disposable Oropharyngeal Airway Models KLT 203
Regulation Number: 868.5110
Regulation Name: Oropharyngeal Airway
Regulatory Class: I
Product Code: CAE
Dated: March 17, 2004
Received: March 18, 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.

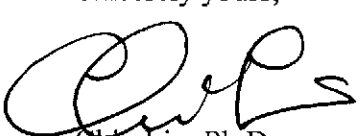
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Attachment I

Indications for Use

510(k) number: K033186

Device name:

KLT 203 Size 3	Small adult disposable oropharyngeal airway
KLT 204 Size 4	Medium adult disposable oropharyngeal airway
KLT 205 Size 5	Large adult disposable oropharyngeal airway

Indications for Use:

The KING LT-D 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

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