Laerdal
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K954771/S1
2-6-96

January 31, 1996

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

MAY -9 1996

SENT VIA FAX

Re: Additional information request on K954771, Laerdal Medical Corporation's Trachlight Stylet & Trachlight Wand.

Dear Mr. James Lee:

Per our telephone conversation of January 30, 1996, I am providing you with the following information that you requested.

1. Provide the summary section of the submission.
2. Provide the standard for the mucosal contact of the lightwand.

1. Summary Section of Submission

In accordance with Section 510(K) of the Food, Drug and Cosmetic Act and 21 CFR 807, this premarket notification is being submitted.

1. Classification Name: (78FCQ) Light source, incandescent diagnostic.

   Common Name: Lighted stylet for intubation.

   Proprietary Name: Trachlight Stylet and Tracheal Lightwand

2. Establishment Registration:

   Manufacturer: Laerdal Medical Corporation
   167 Myers Corners Road
   P.O. Box 1840
   Wappingers Falls, NY 12590
   Registration Number: 2425852

3. Device Classification: The device has been classified under Section 513 of the Act as Class II

4. Performance Standards:

Laerdal has reviewed the requirements of Section 514 of the Act and has no reason to believe that any requirements of the section are currently applicable to the device that is the subject of this notification.

5. Labeling:

Included with this notification and enclosed as Attachment 2 is the proposed labeling pertaining to the device, i.e., the immediate product label as well as the operating instructions which would accompany each shipment of the device and the Promotional and advertising materials.

6. Substantial Equivalence:

This device is similar in design, composition, and function to the following products in commercial distribution: (See Attachment 3)

a. California Medical Products, Inc. Stylet and Tracheal Lightwand (now owned and manufactured by Laerdal Medical Corporation) and reviewed on K922842/A.

b. Fiberoptic Medical Products, Inc. Imagica Fiberoptic Lighted Stylet.

c. Aaron Medical Industries, AARON Pediatric Surch-Lite.

The Trachlight is designed to facilitate the placement of endotracheal tubes of various sizes and lengths for both orotracheal and nasotracheal intubations. The Trachlight includes a wand with an incandescent light bulb at its tip that is placed inside the endotracheal tube prior to intubation, with the light bulb positioned at the end of the endotracheal tube. Light from the light bulb helps provide a guide for the clinician during the intubation process, and light emanating from the light bulb can be seen through the patient's tissue when the end of the endotracheal tube is properly positioned in the patient's trachea.

The Trachlight consists of a reusable handle that contains the batteries and electronic circuits to apply power to the light bulb; a sterile, flexible wand that contains the light bulb at the tip; and a stylet that slides into the wand and acts as a stiffening member when needed. With the stylet inserted, the wand is more rigid and will retain its shape (e.g. for orotracheal intubation). With the stylet removed, the wand is more flexible (e.g. for nasotracheal intubation).

The Trachlight device is non-critical and non-life supporting. Primarily it is a product of convenience for the clinician who is responsible for intubating a patient. The Trachlight makes the procedure of endotracheal intubation simpler, easier, and usually quicker than the current standard practice of using a laryngoscope. The Trachlight can be used in

conjunction with a laryngoscope to augment that method, or can aid endotracheal intubation without the use of a laryngoscope.

Both the laryngoscope and the Trachlight use a battery powered light bulb to aid visualization. Loss of light due to the failure of the light bulb or connecting circuits presents the same inconvenience in both instruments, and such a light output failure presents no greater risk in the case of the Trachlight than for the laryngoscope.

The Trachlight shaft and lighted tip are placed inside of the Endotrachial (ET) tube, and thus are not in direct contact with the patient in normal use. Some mucosal contact is possible at the tip of the ET tube if the Trachlight tip is mispositioned by the user and placed forward of the tip of the ET tube. All Trachlight material which can contact the patient will/has been qualified biocompatible in accordance with USP class V (mucosal contact) or higher.

Even though the tip of the Trachlight will not normally contact the patient, the temperatures at the tip of the Trachlight are limited and do not exceed the UL Standard 544 requirements of 50 C. (See attached pages 54 and 55 from UL 544 paragraph 36.2; and attached letter from Dalhousie University dated September 23, 1992, which was provided as additional information in K922842).

2. Mucosal Contact Standard

See attached:
UL 544-1993, pages 54 and 55 paragraph 36.2
Letter from Dalhousie University dated September 23, 1992 and supplied on K922842 as additional information for that 510(k) submission.

Sincerely,

Kenneth B. Herland
Director Regulatory Affairs/Q.A.

Attachments: 3 pages