

K082038

510(k) Summary

Model 30000-V, Video Endoscope

APR 28 2009

General Information

Classifications Class II 21 CFR 868.5730

Product Code BTR

Trade Name Clarus Model 30000-V, Video Endoscope

Submitter Clarus Medical, LLC
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Predicate Devices

Vision-Sciences ENT-5000 and ENT-5100 Video ENT S (K072073)
Karl Storz Video Bronchoscope System (K071530)
Clarus 2127 Murphy Pen (K962255)
ETVIEW Tracheoscopic Ventilation Tube System (TVT), K052233

Date Prepared June 26, 2008

Device Description

The Model 30000-V endoscope is a tubular device with a malleable shaft. The optical element of the endoscope consists of a small diameter camera bonded into the distal tip of the endoscope shaft. The removable shaft of the endoscope is attached to the battery and video screen by means of various electrical connectors. Illumination light is provided at the tip of the endoscope for direct viewing. The removable shaft of the endoscope is soakable and can be high-level disinfected. A waterproof cap is provided to protect the connector during the cleaning/disinfection process.

Indications for Use

The Clarus Model 30000-V Video Endoscope is indicated for visualization of airway anatomy to aid in the placing and confirming placement of artificial airways.

Testing

All materials that may come into contact with human tissue during normal use are biocompatible and are suitable for this application.

Physical testing of the endoscope included: dimensional inspection, visual examination for workmanship, bond strength testing, optical clarity, light transmittance, and distal tip temperature study.

Summary of Substantial Equivalence

The Clarus Model 30000-V, Video Endoscope is substantially equivalent to other FDA Cleared video endoscopes on the market Indicated for Use for the visualization of airway anatomy and to aid in placing and confirming placement of artificial airways. The sizes and configurations of the endoscope available along with the packaging and disinfection methods are also equivalent. See devices listed in Table 2

The clinical Indications for Use of the Model 30000-V Video Endoscope are equivalent to those of other FDA Cleared devices listed in Table 2.

Therefore, due to the similarity of materials to other predicate devices, the test results and the equivalent Indications for Use to other predicate devices, Clarus believes this product do not raise any new safety or effectiveness issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2009

Mr. Thomas Barthel
President
Clarus Medical, LLC
1000 Boone Avenue North
Suite 300
Minneapolis, Minnesota 55427

Re: K082038

Trade/Device Name: Clarus 30000-V Video Airway Endoscope
Regulation Number: 21 CFR 868.5730
Regulation Name:
Regulatory Class: II
Product Code: BTR
Dated: April 16, 2009
Received: April 24, 2009

Dear Mr. Barthel:

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K082038

Device Name: CLARUS 30000-V VIDED AIRWAY ENDOSCOPE

Indications For Use:

INDICATED FOR VISUALIZATION OF AIRWAY ANATOMY AND TO AID IN THE PLACING AND CONFIRMING PLACEMENT OF ARTIFICIAL AIRWAYS.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Susan Penner

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082038