

MAY 23 1997

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510(k) Summary

Model 2127-900 Series Endoscope Adapter

General Information

Classifications    Class II Accessory

Trade Name        Clarus Model 2127-900 Series Endoscope Adapter

Submitted         Clarus Medical Systems, Inc.  
1000 Boone Avenue North, #100  
Minneapolis, MN 55427

Contact            Dale Sappenfield  
Vice President Engineering and Quality

Device Description

The Model 2127-900 Series Endoscope Adapter is a machined or molded plastic piece used to hold an endoscope and airway catheter together. The endoscope adapter has a machined or molded tapered hub designed to fit firmly into the proximal end of various airway catheters. Additionally the endoscope adapter has a central hole designed to fit the outside diameter of the shaft on the appropriate legally marketed Clarus Model 2127 Endoscope.

Intended Use

The Model 2127-900 Series Endoscope Adapter is an accessory for the Clarus Medical Systems Model 2127 Endoscope. It is intended to be reusable. It is used to temporarily clamp or hold the endoscope when mounting to an airway catheter.

Testing

Biocompatibility testing was done on the material used in the endoscope adapter. The material passed biocompatibility testing and is suitable for this application.

Physical testing included disinfecting solution (2% glutaraldehyde) exposure testing, examination for workmanship, dimensional measurements and certification of material.

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**Summary of Substantial Equivalence**

The Model 2127-900 Series Endoscope Adapter is an accessory to a Model 2127 Clarus Endoscope. When used with the appropriate endoscope, the endoscope adapter augments the capabilities of the endoscope by acting as a clamping and holding device to temporarily mount the endoscope to and airway catheter.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 23 1997

Mr. Dale Sappenfield  
Vice President, Engineering & Quality  
Clarus Medical Systems, Inc.  
1000 Boone Avenue North  
Minneapolis, Minnesota 55427

Re: K971584  
Clarus Model #2127-900 Series Endoscope Adapter  
Dated: May 13, 1997  
Received: May 16, 1997  
Regulatory class: II  
21 CFR §876.1500/Product code: 78 KOG

Dear Mr. Sappenfield:

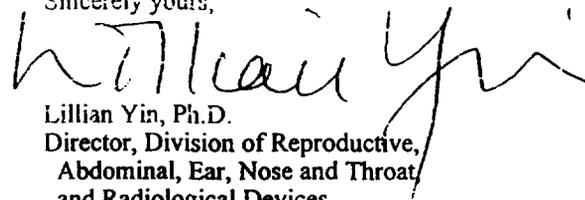
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: CLARUS MODEL 2127-900 SERIES ENDOSCOPE ADAPTER

Indications For Use:

ENDOSCOPE ACCESSORY USED TO TEMPORARILY MOUNT AND HOLD AN APPROPRIATE ENDOSCOPE AND AIRWAY CATHETER TOGETHER

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Nathan  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K971554

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)