

JUL 28 1998

K981827

P1071

Safety and Effectiveness Summary

The functional package of this unit is as safe as separated components used for general endoscopy. The illuminator for all such systems presents the biggest question mark. This system utilizes a low wattage (28 watt) lamp instead of the usual 150 watt or 300 watt lamp usually used for such applications. This lower wattage provides several safety advantages:

- Longer life (150 hours vs. typically 40 hours).
- Low energy at the light guide end virtually eliminating problems with burning and end tip heating which is common with other systems. (The system has the same hot mirror configuration as other systems.)
- 3400°K color temperature.
- Better utilization of the available light because the filament is smaller and capable of being focused to a smaller point on the fiber optic bundle.

The fact that the system is completely pre-wire internally eliminates delays in a procedure because the video equipment was not connected correctly. The use of a single cord minimizes potential problems with tripping over multiple cords.

The fully assembled system meets the current UL544 current leakage requirements.

The effectiveness of this unit is the same as multi-component set ups when used with more conventional ½" CCD sensors and 150 watt illuminators which is a common combination especially for office applications, into which this system will be marketed.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. John D. Plumadore
Director of Engineering
AngioLaz, Inc.
P.O. Box 556
Industrial Park
Bellows Falls, VT 05101Re: K981827
AngioLaz VES 0281-m Video Endoscopic System
Dated: May 20, 1998
Received: May 22, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 KOG and 78 GCT

Dear Mr. Plumadore:

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/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

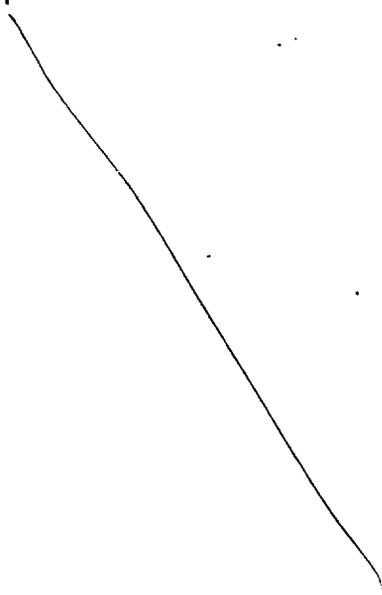
Enclosure

510(K) Number (if known)

Device Name **VES0281-m**

Indications For Use:

VES0281-m is for use as a visual aid for an endoscope when doing diagnostic evaluations or procedures.



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



- Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Sathrig /
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981827

Prescription Use ✓
Use _____
(Per 21 CFR 801.109)
96)

or

Over-The-Counter
(Optional Format 1-2-