

MAY - 7 2004

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Acueity, Inc.
100 Hamilton Avenue, Suite 140
Palo Alto, CA 94301

Telephone: (650) 473-9910
Fax: (650) 473-9306

B. Contact Person

Nancy Lincé
Regulatory Affairs Consultant

Telephone: (650) 759-6186

C. Date Prepared

March 2, 2004

D. Device Name

Trade Name: ViaDuct Miniscope and Accessories
Classification Name: Endoscope and Accessories and Biopsy Instruments and Non-electric biopsy forceps

E. Device Description

Like the predicate devices, the Acueity ViaDuct Miniscope and Accessories consist of a semi-rigid fiberscope with an irrigating outer sheath or introducer capable of passing a biopsy needle to a soft tissue site for view or, to view and assess/biopsy soft tissue. The Acueity ViaDuct Miniscope and Accessories is also designed with an inner grasping sheath or tube that can be placed within the outer introducer, which together act as forceps capable of grasping soft tissue for biopsy. The combination of these devices allows access to very finite spaces.

F. Intended Use

The Acueity ViaDuct Miniscope and Accessories are intended for use by a physician for viewing an interior cavity of the human body through either a natural opening or an incision. The accessory device is capable of grasping soft tissue for biopsy. The instruments are to be used for diagnostic purposes only and are not intended for therapeutic use.

G. Substantial Equivalence

The Acueity ViaDuct Miniscope and Accessories is substantially equivalent to the Acueity (formerly DOFI Communications, Inc.) Miniaturized Biopsy Scope and the Acueity ViaDuct Microendoscope and Accessories, cleared by the FDA under K011189 and K983527, respectively. The design of the ViaDuct Miniscope and Accessories is similar to the predicate device insofar as intended use, principles or operation, anatomical site for viewing and sampling, safety characteristics and physical characteristics.

H. Device Testing Results and Conclusion

All necessary testing was or will be performed on the ViaDuct Miniscope and Accessories to ensure that the product is substantially equivalent to the predicate devices and to ensure that the new device does not have a significant effect on safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Acueity, Inc.
c/o Mr. J.A. van Vugt
KEMA Quality B.V.
P.O. Box 5185
6802 Ed Arnhem
Arnhem,
Netherlands

Re: K040949

Trade/Device Name: ViaDuct™ Miniscope and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCT
Dated: April 27, 2004
Received: April 28, 2004

Dear Mr. van Vugt:

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.

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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) 594-4659. 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,

Miriam C. Provost
for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ViaDuct™ Miniscope and Accessories

Indications For Use:

The Acueity ViaDuct Miniscope and Accessories are intended for use by a physician for viewing an interior cavity of the human body through either a natural opening or an incision. The accessory device is capable of grasping soft tissue for biopsy. The instruments are to be used for diagnostic purposes only and are not intended for therapeutic use.

Prescription Use X AND/OR Over-The-Counter Use
(Part 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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040949