DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

K973035
24 SEP 97

Mr. Kevin T. Spurgeon
Quality Assurance & Regulatory Affairs Manager
Innovative Medical Systems Corporation
55 Steamwhistle Drive
Ivyland, Pennsylvania 18974

Re: K973035
Trade Name: Viola II Dental Camera System
Regulatory Class: I
Product Code: EIA
Dated: August 12, 1997
Received: August 14, 1997

Dear Mr. Spurgeon:

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 requirement, 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) 594-4618. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Statement of Indications for use

The **Viola II Dental Camera system** is designed for use in the following applications:

1. To allow the clinician to provide the patient with accurate information

2. To allow the clinician to provide educational information to the patient as well as other clinical personnel

3. To provide documentation for patient records

4. To assist the clinician in the diagnosis of oral cancer and gum diseases

5. To provide documentation for insurance companies

There are no known contraindications or product warnings for the **Viola II Dental Camera system.**
The end user must insure that any peripheral equipment (i.e. monitor, printer or computer) used with the **Viola II** is approved for medical applications under the respective national regulations.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973035