DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Roger C. Claar, PhD.
Vice President of Operations & Regulatory Affairs
International Imaging Electronics
881 Remington Boulevard
Bolingbrook, Illinois 60440-4932

JUL - 3 1997

Re: K972019
Trade Name: Perfect Shot
Regulatory Class: I
Product Code: EIA
Dated: May 29, 1997
Received: June 1, 1997

Dear Dr. Claar:

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

510(k) Number (if known): **K972019**

Device Name: **Perfect Shot Intra-Oral Camera**

Indications For Use:

The **Perfect Shot Intra-Oral Camera** is to be used by medical practitioners, usually dental hygienists, assistants or dentists, to view the mouth of patients. It can explore the entire mouth and examine teeth or gum tissue for diagnostic purposes. It is distributed through dealers to medical practitioners.

The **Perfect Shot** is wireless, unlike other similar devices, allowing more freedom of movement by the user. It also contains voice activated instructions which enable the user to "freeze" a view on the monitor or take a picture (capture and print) of the area being examined for reference at a later date by simply using voice instructions.

The product is designed to transmit a RF (radio frequency) signal to a receiver. This product can and will be used both intra and extra orally, which will allow a dentist to examine and display to the patient problem areas of concern or treatment that is required. The resolution capabilities of the CCD (Charge Coupled Device) is 640-480 lines.

The picture is transmitted to a monitor in the examination area for the patient to view, allowing the patient a better understanding of a potential problem and a better explanation of the prescribed solution.

Pictures that are captured may be printed for further review or for patient files. The **Perfect Shot** may also be attached to computers for digital storage or transmission to other computers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972019

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)