FDA NEWS RELEASE

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FDA investigating illegal online sale of handheld dental X-ray units

Devices could be dangerous due to unnecessary radiation exposure

The U.S Food and Drug Administration is warning dental and veterinary professionals to not purchase or use certain potentially unsafe hand-held dental X-ray units. The FDA is concerned that these devices may not be safe or effective and could expose the user and the patient to unnecessary and potentially harmful X-rays. The units, sold online by manufacturers outside the United States and directly shipped to U.S. customers, have not been reviewed by the FDA and do not meet FDA radiation safety requirements.

The Washington State Department of Health alerted the FDA after tests on a device purchased online revealed it did not comply with X-ray performance standards.

As a result, FDA is investigating the extent of the problem and notifying state regulatory authorities, dental professional organizations and other health organizations about the safety risks. To date, no adverse events have been reported.

A hand-held dental X-ray unit is a small, portable device that is intended for dental X-ray examinations. All units that have been cleared by the FDA bear a permanent certification label/tag, a warning label, and an identification (ID) label/tag on the unit. Use of these devices requires a prescription from a licensed practitioner.

“Health care professionals using these devices should verify they are purchasing and using those that have been reviewed and tested to meet FDA’s standards,” said Steve Silverman, director of the Office of Compliance in the FDA’s Center for Devices and Radiological Health.

To ensure this, users should:

• Verify the presence of required labels on the device.
• Ask vendors whether the device has been reviewed and cleared by the FDA.
• Access the FDA Medical Device Approvals and Clearances searchable database to verify that the X-ray unit has been cleared by the FDA.
• Contact their state regulatory agency if they become aware of a device that may be hazardous or does not meet the FDA’s requirements.

The FDA will continue to monitor this problem and keep the public informed as new information becomes available. Questions about this alert can be directed to the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

For more information:
FDA: Medical Devices

How FDA Regulates Veterinary Devices

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.