Hand-held Dental X-Ray Units: FDA Safety Communication - Unreviewed Products May Not Be Safe or Effective

U.S. Food & Drug Administration

AUDIENCE: Dentistry

ISSUE: FDA notified healthcare professionals, including dentists, dental care professionals and veterinarians, about the illegal sale of hand-held dental X-ray units that have not been reviewed by the FDA. The FDA is aware of hand-held dental X-ray units being sold online by manufacturers outside the U.S. and directly shipped to customers in the U.S. These devices may not be safe or effective and could potentially expose the user and the patient to unnecessary and potentially harmful X-rays.

BACKGROUND: All hand-held dental X-ray units that have been certified by the manufacturer to meet the FDA's radiation safety standards bear a certification label/tag, a warning label, and an identification (ID) label/tag on the unit's housing. All labels/tags should be in the English language and permanently affixed or inscribed on each product so that they are legible and readily accessible when the X-ray unit is fully assembled for use.

RECOMMENDATION: Healthcare professionals should:

- Verify that your device bears certification, warning and ID labels as described in the FDA Safety Communication.
- Ask your vendor whether the device has been reviewed and cleared by the FDA.
- Access the FDA Medical Device Approvals and Clearances searchable database [1] to verify that the X-ray unit you are using has been reviewed by the FDA.

If you become aware of a device that you think is hazardous or does not meet FDA's radiation safety or premarket clearance requirements, contact your state regulatory agency, which will then notify the FDA. The Conference of Radiation Control Program Directors (CRCPD) [2] website has a list of contacts for each state.

[02/09/2012 - Safety Communication [3] - FDA]

SOURCE [4]

Source URL (retrieved on *04/24/2015 - 10:21pm*):
http://www.mdtmag.com/news/2012/02/hand-held-dental-x-ray-units-fda-safety-communication-unreviewed-products-may-not-be-safe-or-effective?qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/ucm2007460.htm
[2] http://www.crcpd.org/Map/RCPmap.htm
[3] http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/AlertsandNotices/ucm291214.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm291539.htm