

### FDA investigates handheld dental x-ray units (3/12)

A press release issued by the U.S. Food and Drug Administration (FDA) warns dental and veterinary professionals to not purchase or use certain potentially unsafe hand-held dental X-ray units. According to the FDA, the units were sold online by manufacturers outside the United States and shipped directly to U.S. customers but the units have not been reviewed by the FDA and do not meet FDA radiation safety requirements. 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. 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. The FDA advises that you should verify when purchasing or using these devices that they have been reviewed and tested to meet FDA's standards by doing the following:

- Verify the device has the required labels
- 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 your state regulatory agency if you become aware of a device that may be hazardous or does not meet the FDA's requirements.



**Aribex, Inc., manufacturer of the NOMAD handheld x-ray devices stated that their units are legal and not the subject of the FDA investigation.** The FDA investigation involves the illegal online sales of handheld dental and veterinary x-ray units by manufacturers outside the United States. Aribex stressed that the NOMAD®, which is manufactured in the United States, is proven safe and FDA-cleared. The FDA will continue to monitor this problem and keep the public informed as new information becomes available. More information on this alert can be found at the following link:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm291373.htm>