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## Use Caution When Purchasing a Handheld X-ray Device On-line

It looks so good on the internet auction website: For around \$875, you can own a hand-held portable wireless dental X-ray unit. Other models are selling for over \$2,000. What a deal, right? Probably not when it comes to the legality of the X-ray unit.

Handheld dental X-ray units that do not bear the U.S. Food and Drug Administration's (FDA) seal of approval could be emitting dangerous levels of radiation, especially if they are purchased online from overseas manufacturers or distributors.

We have recently discovered some handheld X-ray devices that were purchased on-line that are not approved by the FDA. When one of these units was tested, the actual X-ray exposure was much higher than expected.

When purchased off an auction-type website, it can be almost impossible to determine if these devices are FDA approved. A reputable dealer is the best option. However, there are a few ways to check for FDA approval. The device can be checked for FDA approval at this link:

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm>

The following label is required to be affixed to the approved device:

“Designed and manufactured in compliance with IEC 60601-1, 60601-1-1, 60601-1-2, 60601-1-3, 60601-2-7, and DHHS Rules 21 CFR Subchapter J, applicable at date of manufacture.”

A warning label on the X-ray panel should state these exact words: “This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.”

If you would like more information or would like assistance determining if a device is approved for use in the United States, please contact the Idaho Radiation Control Program at 208-334-0528.