

## FDA & Medical Device Data Systems (MDDS)

On February 9, 2015, the Food and Drug Administration (FDA) issued *Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for Industry and Food and Drug Administration Staff (The Guidance)*. The Guidance does not create or confer rights, nor does it bind either the FDA or the public. It merely provides the FDA's current thinking on the topic, and should be looked upon as recommendations.

### Purpose of the Guidance

Inform manufacturers, distributors and other entities that the FDA does not intend to enforce compliance with the regulatory controls that apply to Medical Device Data Systems (MDDS), medical image storage devices and medical image communications devices.

### What does enforcement discretion mean?

The FDA does not intend to enforce compliance with regulatory controls, including registration, listing, premarket review, post-market reporting and quality system regulation.

### Why has the FDA made this decision?

In Feb. 2011 the FDA eased regulatory requirements on MDDS manufacturers by down-classifying MDDS from Class III (high-risk) to Class I (low-risk). Since then, the FDA has become more familiar with the technology and has come to the conclusion that due to the low risk they pose to patients and the importance they play in advancing digital health, they do not intend to enforce compliance with regulatory controls.

### What is a MDDS?

MDDS is a device that is intended to transfer, store, convert or display medical device data without controlling or altering the functions or parameters of any connected medical devices. An MDDS may include software, electronic or electrical hardware, modems, interfaces, and a communications portal.

Notably, this definition does not include devices intended to be used in connection with active patient monitoring.

### What types of devices are considered used for “active patient monitoring” and still a focus of the FDA’s oversight?

Devices used for “active patient monitoring” include devices that monitor patients in situations where the context or condition require a timely response.

For example, a nurse telemetry station that receives and displays information from a bedside hospital monitor; or a device that displays information from a monitoring device in a patient’s home and is intended to prompt an immediate response.

Devices that are not involved in “active patient monitoring” do not require an immediate response. For example, an application that transmits a child’s temperature to a parent while the child is in a school nurse’s office.