
TELEMEDICINE STETHOSCOPES

Does Your Telemedicine System Require FDA 510(k) Approval?

Looking for clarification around FDA 510(k) requirements for using a stethoscope for telemedicine?

Telemedicine stethoscopes go beyond electronic stethoscopes. Not using a stethoscope where both the stethoscope and software are cleared by the FDA specifically for telemedicine may place the practitioner at risk for needing 510(k) clearance for their cart or other telemedicine system components.

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Electronic Stethoscopes, Telemedicine Stethoscopes and MDDS

FDA Ruling on MDDS

Medical Device Data Systems (MDDS) are hardware or software products that transfer, store, convert formats, or display medical device data. An MDDS does not modify the data or modify the display of the data, and it does not, by itself, control the functions or parameters of any other medical device. MDDS are not intended to be used for active patient monitoring and devices used in healthcare situations that meet these criteria have generally been down-classified by the FDA to Class I Medical Devices. Further, due to the low risk associated with MDDS, the FDA does not intend to enforce compliance with the regulatory controls for MDDS that normally would apply to Class I devices.

Generally, straightforward videoconference systems with remote cameras such as otoscopes or general examination cameras do not require FDA 510(k) approval so long as they meet the MDDS criteria.

It is important to note that a fundamental characteristic of an MDDS is that it only handles data that is already in digital format. If a system processes analog medical device data to get it into digital format, then that function is not an MDDS function, but is considered an "accessory" to the medical device itself.

FDA Ruling on "Accessories" to Medical Devices

Specifically, if the PC in a telemedicine system converts an analog stethoscope signal to digital format (i.e. analog-to-digital conversion, encoding and formatting), then that is considered accessory to the electronic stethoscope, which is a Class II medical device. Therefore, that function is required by the FDA to have 510(k) approval. FDA approval can be obtained by the stethoscope manufacturer or by the provider of telemedicine cart/PC, but it must be obtained to be in compliance with the FDA.

By using electronic stethoscopes that have not been approved for telemedicine, many telemedicine providers may have inadvertently put themselves in conflict with FDA rulings.

Current Landscape of Telemedicine Stethoscopes

The electronic stethoscope market has largely been focused on physician office use or for a home "tool" using store and forward technology. Electronic stethoscopes have always required 510(k) clearances as Class II medical devices. Lately, there have been new companies entering the market that appear to think they are exempt based on old FDA proposed regulations in 2014 that were corrected and updated months later.

The confusion in regards to regulations around electronic stethoscopes has been compounded by the recent explosion of telemedicine. While most electronic stethoscopes in the marketplace have the required 510(k) clearance for their device, most do not possess the required 510(k) clearance on the PC related signal processing technology which is considered an "accessory" to the stethoscope.

There have been recent new entrants to the market such as Eko Devices that have gone through the rigorous process for FDA 501(k) clearance for its store and forward technology. However, there are only

two electronic stethoscope manufacturers that have FDA clearances specifically covering telemedicine - RNK Products, Inc. (Telehealth Technologies) and Littman (formerly 3M Littman). Below is an overview of the major electronic stethoscopes currently on the market and their FDA compliance status:

Manufacturer	Stethoscope Model	Hardware FDA Cleared	Software FDA Cleared for Telemedicine	Intended Use Case	Notes
RNK Products	PCP-USB	YES	YES	Institutional & Home Telemedicine	Additional one-time software license fee.
Littmann	3200	YES	YES	Physician's Office, Institutional Telemedicine	Bluetooth only. Additional license fees and ongoing cloud service. Requires two units (one at patient end and one at clinician end).
Thinklabs	One	YES	NO	Physician's Office	Telemedicine cart assumes FDA responsibility.
Cardionics	E-Scope	YES	NO	Physician's Office	Telemedicine cart assumes FDA responsibility.
Eko Devices	Eko Core	YES	SORT OF*	Physician's Office	Bluetooth to iPhone only; Monthly fee for cloud service.
CliniCloud	CliniCloud	NO	NO	Home	Works with an iPhone. Part of a home kit with a thermometer.

*Eko Core's original 501(k) was for store and forward.

Six Questions to Ask Your Telemedicine Integrator

The regulations around electronic and telemedicine stethoscopes aren't always obvious. Here are six questions to ask your telemedicine integrator:

- 1) Is the hardware cleared as Class II by the FDA?
- 2) Is the software signal processing also cleared as Class II by the FDA?
- 3) What is covered by the license fee for software?
- 4) What are the ongoing fees for service, if any?
- 5) Is your solution PC based or mobile based? In most health settings, a PC is used as part of an integrated system.
- 6) What is your understanding of the FDA regulations around electronic stethoscopes use for telemedicine? If your telemedicine integrator's response is different than presented in this paper, call (or e-mail) the FDA and get your information directly from the source.

FDA Contact Information

The FDA is far more accessible than some people think. For further information, contact the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH). E-mail at DICE@fda.hhs.gov or call at 1.800.638.2041.