FDA Requirements for Telemedicine Stethoscopes

Telemedicine stethoscopes have additional FDA regulatory requirements relative to typical electronic stethoscopes for office use. In determining approval for telemedicine use, the FDA includes signal processing as well as data transport in its considerations.

It is important to note that not every FDA cleared electronic or digital stethoscope is FDA approved as a telemedicine stethoscope. Further, if any of the stethoscope signal processing is performed by the PC or other software component of the telemedicine system, then those elements are classified by the FDA as accessory elements to the stethoscope and must also have FDA 510(k) clearance. Thus, when using an electronic or digital stethoscope that is not a cleared telemedicine stethoscope, a telemedicine system provider could be inadvertently operating against FDA regulations.

Discussion

Remote auscultation involves two distinct software elements on the PC:

Stethoscope signal processing. The stethoscope signal processing includes digitizing and encoding the signal plus using selectable filters to aid the physician in focusing on sounds of different frequencies such as heart vs lung sounds. Under current regulations, these signal processing functions must be FDA cleared as "accessory" elements to the electronic stethoscope itself.

Network transport of the digitized stethoscope signal. The digitized stethoscope data stream can be merged with the video conferencing stream and allow a telemedicine integrator’s existing video conferencing equipment to manage the network connectivity between physician and patient sites. Conversely, the transport can be handled by dedicated software over its’ own connectivity channel. In either case, FDA clearance will be required if the signal is altered in any way in transport or storage. Without signal alteration, MDDS rules apply and Class II approval is not a requirement for the transport element.

For an electronic stethoscope with an analog connection to the microphone port of a PC to be used in a telemedicine application requires use of certain functions of the PC - specifically, the audio amplifier, analog-to-digital conversion (ADC), encoding and formatting the digital signal for transmission over the Internet. Since those elements are essential to implement the telemedicine application, then those elements can be considered as an "accessory" to the stethoscope for telemedicine. According to FDA rules, accessory items must be approved under the same classification as the core device, which for an electronic stethoscope is Class II.

The accessory can have its own 510(k) or be included in the 510(k) for the stethoscope. No matter which element has it, the amplifier, analog-to-digital converter (ADC) and encoder for the analog stethoscope signal must have 510(k) clearance.

In the case where an analog electronic stethoscope that has FDA clearance for the stethoscope itself but not the PC signal processing part, FDA rules apply to the PC of a telemedicine cart when the stethoscope plugs into its audio port. Without a 510(k) on the PC’s signal processing, that cart is in violation of FDA rules.
PCP-USB Stethoscope and Software

RNK Products has designed its stethoscope hardware and software concurrently with telemedicine as the core application and has obtained FDA approval for the accessory software functions and use in the telemedicine setting as an integrated Class II Medical Device.

The PCP-USB Chest Piece picks up a body’s auscultation sounds, amplifies them, digitizes them, codes them into a linear PCM stream, then puts the signal into USB format that a PC recognizes as a USB Microphone input. Issues about FDA approval arise when the PCP-USB is used in a telemedicine application where the signal is transported from one location to another.

The digital signal from the PCP-USB can be transported by a Medical Device Data System (MDDS) to another location to implement a telemedicine system. But the MDDS can only transport the signal; it cannot alter the medical data content. A typical telemedicine cart is an MDDS device. Simply plugging in a stethoscope to the MDDS does not guarantee that the signal will not be altered in transport.

Part of the sSOIP Anywhere software alters the auscultation signal in that it can invoke filters, change coding schemes and provide local loopback and store the data stream from a stethoscope session. Because of this, sSOIP Anywhere is classified as a Class 2 Medical Device, the same as the PCP-USB Chest Piece and both have been approved by the FDA. The other part of sSOIP Anywhere provides data transport (without altering the auscultation signal content) similar to what an MDDS might do.

The newer PCP-SSP software also performs stethoscope signal processing functions and is approved by the FDA as an accessory element in the 510(k). Because PCP-SSP is FDA cleared software, telemedicine system providers can feel secure in their FDA regulatory compliance when using the PCP-USB stethoscope with the PCP-SSP software on their telemedicine carts and systems.

It can be debated as to whether or not the FDA will decide to enforce existing rules as to what is and isn’t an MDDS but the PCP-USB stethoscope and, either the sSOIP Auscultation Anywhere software or the newer PCP-SSP software, when used together, are both FDA approved Class II Medical Devices. If those are installed on a cart or system, one significantly mitigates the risk that the system could be judged more than a Class I MDDS due to signal transport issues from the stethoscope or VC platform.