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Action Alert

Topic	Misleading Promotional Tactics by Medtronic Regarding Pulse Oximeter Sensors
Market Area	U.S. and Canadian Hospitals & Health-Systems
Product(s)	Medtronic Nellcor™ "Remanufactured" Pulse-Oximeter Sensors (Product Code NLF)
Date	June 12, 2025

Issue(s)

Issue 1: False marketing designation. Medtronic markets reprocessed Nellcor™ pulse oximeter sensors as "remanufactured." Under 21 C.F.R. § 820.3(w), FDA defines "remanufacturer" as "…any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device **that significantly changes the device's performance or safety specifications, or intended use**." (*Emphasis Added*). Medtronic does not meet this definition, nor has FDA given Medtronic the authority to use this designation.

Medtronic has FDA clearance to **reprocess** Nellcor™ sensors (product code NLF, 501k clearance K033973 "oximeter, reprocessed"), not to **remanufacture** them.

Medtronic uses the false remanufacturing label to intentionally mislead hospitals into believing that it is the only firm cleared to offer a remanufactured Nellcor™ sensor—a claim created to confuse the market and misrepresent availability of FDA regulated, reprocessed sensors that use the identical product code.

AMDR issued a Cease-and-Desist letter to Medtronic on this issue and filed a Trade Complaint with FDA as well.

Issue 2: False marketing claims. On its marketing webpage, Medtronic makes false claims that it "remanufactures" these devices to be "100 % like-new," and "equivalent to new." This language runs contrary to FDA guidance for remanufactured or reprocessed devices, which are "substantially equivalent" to their predicate device. Medtronic appears to use this language to mislead customers to believe that their "remanufactured" sensor is superior to 510(k)-cleared "reprocessed" alternatives. These claims have no peer reviewed evidence to support them.

Be aware that Medtronic sales representatives may share a marketing webpage that uses unlawful promotional tactics, including claims of superiority over FDA-cleared third-party reprocessed devices (same NLF product code), without adequate substantiation or third-

party validation. Medtronic falsely asserts it is the only firm cleared to reprocess Nellcor™ sensors—a claim that misrepresents market availability to hospital buyers.

Issue 3: Use of junk science. Medtronic's performance claims rely on an unpublished, internally created white paper used to justify misleading marketing claims. The paper lacks transparency, independent validation, and contradicts FDA definitions.

The white paper continues a pattern at Medtronic of what we believe to be misleading use of marketing materials disguised as scientific papers. Medtronic used similar false and misleading tactics in 2024 about the LigaSure™ product line. AMDR issued a separate Cease and Desist letter to Medtronic on this matter.

Issue 4: Greenwashing. Further, Medtronic's FDA clearance to reprocess each sensor allows for only one cycle before it must be discarded. AMDR members have presented validation data to FDA, which the agency has accepted, making clear the devices can be "turned" multiple times.

On its website, Medtronic misleads the marketplace by claiming the single turn is a result of its rigorous "remanufacturing" process implying that "reprocessing is unable to replicate their high standards that show it can only be turned once.

FDA has reviewed extensive validation data from multiple reprocessors and finds that the devices can be reprocessed for multiple cycles. The only peer reviewed study that measures the cradle to grave impact of a Nellcor™ pulse oximeter finds that the reprocessed version emits 53% less greenhouse gas emissions than its virgin counterpart (using the Max-A product reprocessed by Stryker's Sustainability Solutions in the study). Each time a customer uses a Medtronic reprocessed sensor, it reaches the end of its life resulting in significantly more greenhouse gas emissions.

These tactics reflect a recurring pattern of anti-competitive behavior that misleads providers into thinking reprocessed devices from competing companies have a different level of FDA review or are inferior.

Technical Background

- FDA defines *remanufacturing* as work that "significantly changes" a device's performance, safety specifications, or intended use—criteria that Nellcor™ reprocessed sensors do not meet.
- FDA has a specific product code, NLF, for reprocessed oximeter sensors. Medtronic's clearance is under this product code, meaning it is "reprocessed," not remanufactured. Like other reprocessed devices, reprocessed pulse oximeters are subject to the same regulatory standards and requirements as new devices.
- Medtronic's use of the term "remanufactured" conflates regulated reprocessing with unregulated reuse, falsely misleading buyers into thinking reprocessed sensors are less safe than "remanufactured" ones.
- Medtronic has been cleared by FDA to reprocess their sensors for one reprocessing cycle. AMDR members are often cleared to reprocess these same devices for more

cycles. By reprocessing once and disposing of the device, hospitals partnering with Medtronic are not achieving maximum value from their reprocessing program.

- Making unsubstantiated superiority claims violates FDA misbranding rules at 21 C.F.R. § 801.6 and can trigger Lanham Act liability for false advertising and disparagement.

Recommendations

1. **Partner with trusted reprocessors.** We urge our healthcare partners to partner with AMDR member reprocessors. They adhere to a code of conduct that ensures ethical, transparent, and pro-provider practices, among other things, and do not engage in false or misleading marketing behaviors such as these. AMDR and its member reprocessors can also provide clarity on regulatory status and help defend against misinformation.
2. **Verify that Medtronic's claims are FDA-supported.** Confirm whether product descriptions are consistent with regulatory filings (e.g., 510(k) clearances). Ask to see Medtronic's clearance or look it up on the FDA's website (product code NLF, "Nellcor" as applicant). If it says "reprocessed," and not "remanufactured," you have been misled.
3. **Request substantiating evidence.** Ask for peer-reviewed, third-party validation when Medtronic or other manufacturers make safety or efficacy superiority claims in what appear to be scientific papers. If these papers are not peer-reviewed or independent, you may have been misled.
4. **Maintain zero tolerance for misinformation.** Consider the motivation of sales reps that push misleadingly marketed devices or disseminate false and misleading science.
5. **Continue using FDA-cleared reprocessed devices.** All products under Product Code NLF meet FDA standards for safety and effectiveness, regardless of brand origin. Continue purchasing FDA-regulated, commercially reprocessed devices to safeguard supply chain resilience and cost and carbon savings. Avoid single-vendor dependency created by fear-based marketing.
6. **Be mindful of the number of turns for which a reprocessed device is cleared.** Maximizing reprocessing cycles within FDA regulations maximizes the cost and carbon savings of your reprocessing program.
7. **Report misleading claims.** If you encounter suspicious or unsubstantiated marketing, report it to hospital compliance leadership. Forward copies to AMDR or FDA CDRH.

For Further Information

Click here to read AMDR's Cease-and-Desist letter sent by AMDR to Medtronic. Click here for AMDR's Trade Complaint to FDA.

Contact your AMDR member commercial reprocessing partner for information about FDA regulated, reprocessed Nellcor™ pulse oximeters.

If you have questions or if you are aware of false and misleading marketing schemes to thwart reprocessing, please write to info@amdr.org. If requested, your anonymity will be honored.