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June 4, 2025

BY ELECTRONIC MAIL

Geoff Martha
Chairman & CEO
710 Medtronic Parkway
Minneapolis, MN 55432-5604
Phone: 673-514-4000

geoffrey.martha@medtronic.com.

Re: Cease and Desist: All Medtronic Illegal Promotional and Marketing Tactics Regarding Remanufactured Pulse Oximeter Sensors

Dear Mr. Martha and Team:

We write on behalf of our client, the Association of Medical Device Reprocessors (AMDR)[1], to demand that your company, Medtronic USA, Inc. (Medtronic) immediately cease and desist from engaging in illegal promotional activities and market tactics involving false and misleading claims - specifically those that compare its Remanufactured Pulse Oximeters, Nellcor™ single use devices (SUDs)[2] (hereafter, "Nellcor™" or "Remanufactured Pulse Oximeters") to 510(k)-cleared, substantially equivalent reprocessed versions of those devices.

As discussed in detail below, the comparative claims Medtronic makes are false and misleading

[1] AMDR is the non-profit trade association representing the global "single-use" device reprocessing industry. AMDR members serve over 9,400 hospitals and surgical centers in the U.S., Canada, and 17 other countries. All *U.S. News & World Report* list of America's "honor roll" hospitals are reprocessing with one of AMDR's members. AMDR's core mission is to promote regulated, commercially reprocessed SUDs. In Europe, reprocessing is referred to as remanufacturing. For more information visit www.amdr.org

[2] The Pulse Oximetry Sensors are listed at https://www.medtronic.com/en-us/healthcare-professionals/specialties/acute-care-monitoring/product-portfolio/nellcor-pulse-oximetry-sensing.html (last accessed May 9, 2025).

because they compare "remanufacturing" to "reprocessing, " make superiority claims between reprocessed Pulse Oximeters and Nellcor™ "Remanufactured Sensors," and base comparisons and claims upon a self-serving and self-funded "study" wrought with bias and conflicts of interest. Specifically, Medtronic claims to be "remanufacturing" these SUDs, but in reality, it is simply "reprocessing" Pulse Oximeters. Alternatively, you appear to be doing this without 510(k) clearance for remanufacturing. Thus, you are in violation of the U.S. Food and Drug Administration (FDA) requirements, the Lanham Act, and common law.

Depending on the appropriateness of Medtronic's actions in response to this letter, we will discuss suitable legal remedies with our client.

Medtronic's Illegal Promotional Activities

You falsely claim that the Nellcor™ is being remanufactured when it appears your clearance is under Product Code NLF - Reprocessed Oximeter (K033973).[3] ***Nellcor™ is clearly a reprocessed SUD, not a remanufactured SUD.*** Your claims for remanufacturing, appear to be based on a white paper, "Medtronic Remanufactured vs Third-Party Reprocessed Pulse Oximetry Sensors: a Comparison of Performance and Process Quality"[4] ("White Paper") assessing the performance and process quality of Nellcor™ to third-party reprocessed sensors (specifically from Stryker® and Medline®).

The White Paper was written in-house by Medtronic's paid staff. To the best of our knowledge, it has not been published, nor gone through the rigors of independent peer review, and the chain of custody for the alleged product studied by other reprocessors is unaccounted for. Based in part on this White Paper, Nellcor™ makes claims[5] about remanufacturing. However, the White Paper demonstrates that Medtronic conducted performance testing internally, without involving third parties. Additionally, the paper lacks any methodology detailing where Medtronic sourced the devices. It also fails to address potential biases or protections against conflicts of interest. Furthermore, the paper distinguishes between remanufacturing and reprocessing in a manner that contradicts both their clearance and FDA's regulations and interpretations of these definitions. Lastly, while the paper lists several proprietary procedures for Nellcor™, it does not mention any procedures for Stryker® and Medline®.

Outside of the White Paper, Medtronic's website[6] also makes false promotional claims, including, but not limited to:

1) "Nellcor remanufactured sensors meet original performance and quality specifications.

[3] 510(k) Premarket Notification. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K033973.
[4] Anu Tuladhar, Engineer I and Linden Reustle, Principal Electrical Engineer (Research and Development, Patient Monitoring, Medtronic), "Medtronic Remanufactured vs Third-Party Reprocessed Pulse Oximetry Sensors: a Comparison of Performance and Process Quality," 2024. https://www.medtronic.com/content/dam/medtronic-wide/public/united-states/products/patient-monitoring/pulse-oximetry-sensors-medline-reprocessing-white-paper.pdf.
[5] The Pulse Oximetry Sensors are listed at https://www.medtronic.com/en-us/healthcare-professionals/specialties/acute-care-monitoring/product-portfolio/nellcor-pulse-oximetry-sensing.html (last accessed May 9, 2025).
[6] *Id.*

They are 100% like-new…".

2) "Nellcor™ remanufactured sensors" …"….Designed to provide **sensors equivalent to new** terms of compliance to original product specifcations[§,1]"

Since Nellcor™ does not appear to actually meet the definition of remanufactured (discussed below), the distinction that you are making between remanufacturing and reprocessing appears to be a "marketing" distinction rather than a regulatory one. With these marketing tactics, you are providing consumers with false and intentionally and purposefully confusing information that Nellcor™ is better than these reprocessed SUDs.

We are aware of similar tactics by your company in 2004 and 2008 with similar Medtronic-funded studies about reprocessed Octopus cardiac tissue stabilizer devices and in 2024 about the LigaSure™ product line.[7] This ongoing pattern demonstrates investment in research intended to mislead practitioners and purchasers and inhibit FDA-regulated reprocessing. This is an illegal promotion that must cease immediately.

Violations of FDA Regulations

Federal medical device labeling requirements prohibit comparative claims that are false and misleading when "[a]mong representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device…".[8] For such comparisons ***not*** to be false or misleading, FDA has long required reliable data to substantiate such claims. FDA has advised through Warning Letters that comparative claims are false or misleading because data do not demonstrate that the device is superior to a competing device. FDA has also warned that before a manufacturer may make a direct superiority comparison to another device, adequate and well-controlled studies comparing the device are required.

Additionally, FDA provides guidance, "Remanufacturing of Medical Devices"[9] ("Guidance") and references the definition of "remanufacturing" as "…the processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished device ***that significantly changes the finished device's performance or safety specifications, or intended use***" (emphasis added).[10] Furthermore, the scope of the Guidance only addresses activities performed on devices that are intended to be reused and maintained.

Your claims are false and misleading, as the Remanufactured Pulse Oximeters are not intended to

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[7] *See* The LigaSure™ product line is listed at https://www.medtronic.com/covidien/en-ca/products/vessel-sealing.html (last accessed May 13, 2025), and include LigaSure™ Retractable L-hook Laparoscopic Instrument, Blunt Tip Open and Laparoscopic Sealer/Divider, Maryland Jaw Thoracic Sealer/Divider with Nano-coated Technology, Maryland Jaw Open and laparoscopic Sealer/Divider, Tissue Fusion laparoscopic Instrument, Dolphin Tim laparoscopic Sealer/Divider, Exact Dissector, Open Sealer/Divider, Small Jaw Open Sealer/Divider, Tissue Fusion Open Instrument, Dolphin Tip Open Sealer/Divider, Curved Jaw Open Sealer/Divider.

[8] 21 C.F.R. § 801.6.

[9] U.S. Food and Drug Administration, *Remanufacturing of Medical Devices Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff*, Issued May 19, 2024. (Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices).

[10] *See* 21 CFR 820.3(w).

be reused and/or maintained. Thus, you are not permitted to call this "remanufacturing" of SUDs. It seems as though Medtronic is, in fact, simply reprocessing devices and inaccurately calling it remanufacturing. Alternatively, Medtronic appears to be doing this without a 510(k) clearance for remanufacturing.

Notably, Nellcor™ ® claims they are the only company with clearance to reprocess Nellcor™. However, they are not, and this practice is misleading consumers about the market availability of devices.

Thus, the study and claims mentioned above conflict with FDA's standard for substantiation. Therefore, Medtronic is in violation of 21 C.F.R. § 801.6 and must cease action immediately.

Lanham Act Violations

The website and claims are also false, misleading, and unlawful under the Lanham Act and common law. The Lanham Act provides a judicial cause of action to any company aggrieved by a competitor's promotional misrepresentations.[11] "The Lanham Act creates a cause of action for unfair competition through misleading advertising or labeling. Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers."[12] Medtronic's false and misleading claims also constitute common law disparagement.[13]

In addition to the abovementioned violations, these inaccurate claims and marketing definitions you are disseminating could result in safety risks. For example, you seem to be saying only Medtronic can remanufacture the SUDs because third parties are limited to reprocessing. This statement is incorrect; everyone's product (under Product Code NLF) is cleared as safe/effective.

Inaccurate claims are also often considered unsubstantiated safety superiority claims, which may cause a clinician to potentially minimize the importance of other risk mitigation steps when using Medtronic devices.[14] This could result in patient harm as priorities are not properly considered and less safe options are considered.

These claims that are intended to instill fear could also result in hospitals not purchasing safe reprocessed devices and having less inventory, when devices today can suddenly become unavailable due to supply chain issues that can pose risks to patients.

Appropriate Legal Action

The misinformation being disseminated by Medtronic is false and misleading under the FD&C Act, Lanham Act, and common law. This being the case, AMDR respectfully demands

[11] 15 U.S.C § 1125(a)(1)(B).
[12] *POM Wonderful LLC v. Coca-Cola Co*., No. 12-761 (opinion issued June 12, 2014) [573 U. S. 621 (2014)].
[13] *See*, *e.g.*, *Brass Metal Products, Inc. v. E–J Enterprises, Inc. et al., 189 Md. App. 310, 984 A.2d 361*
[14] See, e.g., note 12.

that Medtronic act immediately to remove all illegal promotional and marketing materials. Simultaneously, we ask that Medtronic issue a press release providing truthful and accurate information, through all appropriate media outlets and on its website, stating that it had inappropriately engaged in illegal promotional activities and marketing tactics involving false and misleading claims that compare its Remanufactured Pulse Oximeters, Nellcor™ SUDs to 510(k)-cleared, substantially equivalent reprocessed versions of those devices. We also ask for evidence that going forward, Medtronic will take actions appropriate to ensure that the deceptive statements and materials described above are immediately discontinued, and removed from Medtronic's websites, and that action is taken to prevent future occurrences.

Please advise the undersigned within ***ten (10)*** business days of receipt of this letter of the measures that you have taken and intend to take to comply with this demand. Absent adequate assurances, we reserve all available recourse toward ensuring a level playing field in the medical device market. We look forward to your response.

Sincerely,

J. Mason Weeda, Esq.