



AdvaMed

Advanced Medical Technology Association

February 9, 2023

Honorable Janeen Sollman
Chair, Committee on Energy and Environment
Oregon State Senate
900 Court St. NE,
Salem, OR 97301

RE: SB 542

Dear Chair Sollman,

On behalf of the Advanced Medical Technology Association (AdvaMed), I write today to express support for the amendment to fully exempt medical devices from SB 542. AdvaMed is the largest national trade association representing nearly 450 leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems.

Patient safety is our membership's top priority, and Original Equipment Manufacturers (OEMs) are subject to strict regulations by the Food and Drug Administration (FDA) to ensure patient safety. FDA regulations include implementing quality and safety controls, proper training, and qualification of replacement parts.

We greatly appreciate the current bill recognizes the importance of the FDA's oversight of medical devices and your willingness to further tailor the exemption. The underlying bill includes an exemption for devices approved for sale or use by the FDA. However, approved devices only account for a small portion of those in the market. Not all devices follow the same regulatory pathway and, therefore, may not receive that label. While all devices are regulated by the FDA, some may receive an exemption or clearance label instead. Further clarifying the language to include all products defined by the FDA as a medical device ensures that all medical devices are captured within the exemption.

Thank you for the opportunity to weigh in on this issue and your willingness to clarify the language. Please feel free to reach out with any additional questions.

Sincerely,

Darbi Gottlieb
Director, State Government and Regional Affairs
AdvaMed