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October 08, 2018

The Honorable Senator Michael Sirotkin
Chair, Senate Committee on Economic Development, Housing & General Affairs
Vermont State House
115 State Street
Montpelier, Vermont 05633

The Honorable Senator Christopher A. Pearson
S. 180 Right To Repair Task Force
Vermont State House
115 State Street
Montpelier, Vermont 05633

Dear Senators Sirotkin and Pearson,

The purpose for my letter today is to express the position of BioTek Instruments, Inc regarding the current path to not include medical devices in the S.180 legislation. BioTek fully supports the decision to not include medical devices in the scope of S.180.

For reference, BioTek is a 50-year-old family run business that is a global leader in life science instrumentation. We are a FDA registered medical device manufacturer with about 474 employees worldwide. 289 of our employees are in Winooski designing, manufacturing, servicing and managing our innovative life changing solutions. Our products are equipment used in a dynamic range of research, production and clinical markets. It is exciting to say that thanks to a manufacturer in Vermont, scientists can help doctors determine the specialized level of chemotherapy that should be administered to a breast cancer patient. Our products help crime labs determine the quantity and accuracy of DNA in their forensic investigations. Farms and food manufacturers utilize BioTek products to ensure the safety of the food brought to market. There is a high probability the last time your blood was analyzed it was with a BioTek product. These examples are just a minor demonstration of use for our products.

Ultimately, it is our position that including medical devices in S.180 increases the negative risks of patient outcomes. Due to the FDA regulation of registered manufacturers, medical devices are a trusted tool that have significant impact on the health of patients, including life-saving outcomes. Medical devices are not consumer electronics.

As the Service Director for a medical device original equipment manufacturer (OEM), I experience the regulatory requirements placed upon our organization to ensure the proper performance of our products. Unfortunately, independent service organizations are not required to meet the same level of scrutiny that is required by the FDA. Even independent service

organizations that refurbish/resell medical devices do not meet the level of scrutiny required for design review by the FDA in 21 CFR 820.30. There is a clear gap between the regulatory requirements of the OEM service organization and other service organizations. These requirements are in place to ensure patient safety. Creating a marketplace where service providers do not have the same regulatory requirements increases the risk to patient success.

In addition to BioTek's own service employees stationed across the United States, and the world, we actually do work with other organizations to provide service and support on our products. We expect our partners to meet our requirements so that they too can give customers high quality support. BioTek's reputation for quality is paramount and a value that we cherish. This focus however is not always the primary goal for other OEMs and/or service providers. I have been at customer locations and seen the impact of poor service by unauthorized, unregulated third party providers. In addition to risking performance, the direct cost to the customer increases significantly because additional service is now needed by the OEM.

The innovation in our product design that is valued by customers requires custom calibration tools for service. These specialized tools are also manufactured by BioTek. Allowing anyone to access these tools and information places our proprietary designs at risk. Due to the interplay between hardware design and software design, protecting intellectual property is critical to success in our market. BioTek's innovative patents are significant contributors to our continued growth.

Due to the precision of our products, there is a significant investment in tools, training and parts in order to ensure the performance specifications. Along with our partners, we invest hundreds of thousands of dollars each year to provide training, systems and equipment to our service representatives. An investment that independent service organizations avoid because they do not have same regulatory mandate. They try to perform unqualified service to maximize their financial gains.

In Summary, We recognize medical device OEMs, their customers and independent service organizations all have a responsibility to ensure the best quality and cost for our healthcare system. In order to enhance the success of this system, the FDA reported it will continue to design requirements to ensure cooperation and establish collaborative communities between stakeholders in the medical device marketplace.

BioTek applauds the effort to continually balance the needs of the marketplace with effective legislation. However, the landscape of all types of manufacturers in S.180 is too diverse to apply one solution.

Thank you for the opportunity to express our position.

Sincerely,

Sean M. Jordan