August 5, 2022

Reichert, Inc.
Attention: Elizabeth Schultz
3362 Walden Avenue, Suite 100
New York, NY 14043

Re: BK 170128

Trade/Device Name:	TS Meter-DSP
Regulation Number:	21 CFR 862.2800
Regulation Name:	Refractometer for clinical use
Regulatory Class:	Exempt
Product Code:	PSM

Dear Elizabeth Schultz:

Upon further consideration, we believe this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the Act).

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 862.2800. When listing your device with the Food and Drug Administration (FDA), please use the product code shown above. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

We recommend that you review the limitations to the exemption in 21 CFR Section 862.9. Please note that if you modify your device in future such that you introduce a new indication for use or a different fundamental scientific technology to the above-referenced classification regulation, your device may exceed the limitations to the exemption and may consequently require 510(k) clearance before marketing this device in the United States. Further, if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 862.9(c), your device will require a new 510(k) before marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 862.9.

Please be advised that Title 21 Code of Federal Regulations, Part 807, Subparts A-D, requires all establishments, whether foreign or domestic, that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into or distribution in the U.S. to register and list with the FDA.

If you have any questions regarding the registration and listing requirements, please call 301-796-7400.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Courteny White at 301-796-0636 or by email at courntey.white@fda.hhs.gov.

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research