



K9C2265

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Attachment 8:

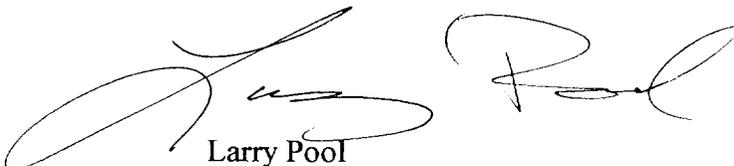
Summary of Safety and Effectiveness for Dynatech Laboratories, Inc.'s
MLX Microtiter® Plate Luminometer

Dynatech Laboratories, Inc. ("Dynatech"), located in Chantilly, Virginia 22021, manufactures and distributes the MLX Microtiter® Plate Luminometer ("MLX"). The MLX is substantially equivalent to other currently marketed microplate luminometers that have received 510(k) premarket notification clearance. Specifically, the MLX is substantially equivalent to the Dynatech ML3000(K923456) and ML2250(K915896) microplate luminometers. The MLX and the predicate luminometers have identical intended uses and there are no differences in technological features that raise new or different issues regarding safety or effectiveness. Under no circumstances does the MLX have any direct patient contact or otherwise perform any therapeutic patient function. The MLX measures the light emitted from bioluminescent and chemiluminescent reactions samples, performs defined test protocols and allows selection of various forms of output formats of the test results.

The Revelation software incorporated in the MLX was developed and manufactured in accordance with comprehensive software development, validation and verification procedures. Through this process Dynatech carefully controls each aspect of the development of software code for the device.

Safety and environmental testing have demonstrated and certified that the MLX conforms to current standards relevant to devices such as the MLX. A hazard assessment study has been MLX and has determined that all known hazards are adequately addressed by device design or user instructions.

Performance testing demonstrates the proper operation of the MLX in accordance with device specifications.



Larry Pool
Quality Assurance Manager