

FDA 510K Compliance

To whom it may concern:

Our Latex, Nitrile & Vinyl exam grade gloves are FDA 510K certified to protect your employees from potential exposure to dangerous substances, contaminated surfaces and contact with patients. Our Exam grade disposable gloves are available in a range of sizes to perfectly conform to your hands for a more comfortable fit.

A FDA 510K certification is a premarket review process used by the U.S. Food and Drug Administration (FDA) to ensure that medical products sold in the U.S. intended for human use are of sufficient quality. FDA 510K approval certifies that a medical product is demonstrably safe and effective at the same levels as approved predicate products.

Satish Gaudani Quality Engineer Wraptite Inc.,