



**Compliance With Good Manufacturing Practice**

In order to assure high quality, safety, and good performance of latex medical gloves, manufactures are required to comply with regulations within various sections of the U.S. Code of Federal Regulations (CFR). The principle section for quality compliance is 21CFR, Section 820. Excerpt as follows:

Sec. 820.1 Scope.

(a) Applicability. (1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices.

Additionally, manufacturing plants must be registered with the FDA and are then inspected by FDA on a regular basis to insure compliance with these regulations.

Most Class II medical devices, such as gloves, must have an FDA approval of substantial equivalence to a pre-marketed device before placing the gloves in interstate commerce. The most widely used type of application is commonly referred to as a, "510(k)". This type of approval allows you to show FDA that the product is substantially equivalent (SE) to a product already 510(k) approved. The application contains sections demonstrating compliance and equivalency to that already marketed "predicate device", for glove safety and effectiveness. There are individual sections of the Code of Federal regulations that deal specifically with the testing requirements of both Patient Examination Gloves and Surgeons Gloves. These requirements must also be included in the 510(k) application for review and approval by FDA.

The areas covered by a 510(k) application include sterilization, labeling, stability, physical and dimensional testing, powder content, leak testing, viral penetration, biocompatibility studies and human subject testing for dermal reactions, latex