



IntelliFill® i.v. Regulatory Status



INTRODUCTION

The FDA exerts regulatory control over medical devices by controlling permission to market those devices and the claims manufacturers can make in their marketing of those devices. In most cases, a device manufacturer must obtain FDA permission to market their device.

The process is similar to that for drugs. A device manufacturer that wishes to market a completely new medical device submits a request for Pre-Market Approval (PMA). If the device is similar in form, function and intended use to other devices already approved by the FDA, there is an abbreviated submission process known by its subsection in the Code of Federal Regulations, a 510(k). To submit a 510(k), the manufacturer must clearly demonstrate the congruence between their device and the *predicate device* already reviewed by the FDA.

The rules by which medical devices are designed, manufactured, marketed and serviced are contained within a set of regulations referred to as the Quality System Regulations (QSR), 21CFR820. The FDA grants a manufacturer permission to market a device if: (a) it can substantiate the claims made in its literature, and (b) the manufacturer can demonstrate that the device was designed, developed, manufactured and serviced according to the QSR. The FDA can temporarily or permanently withdraw that permission if it detects the manufacturer is making unsubstantiated claims, the development or manufacture of the device does not follow the QSR or if public complaints reveal a safety defect in the device.

The FDA, therefore, determines whether or not a device is a medical device (most pharmacy pumps, for example, are not). If a device is determined to be a medical device, it is then classified as Class I, II or III, depending on its level of hazard.

In March 2001, the FDA announced designation of a special subgroup of Class II devices it referred to as Pharmacy Compounding Devices, and stipulated that manufacturers of such devices were no longer required to submit for pre-market approval. The original occupants of that subgroup were TPN compounders.

INTELLIFILL i.v. AS A MEDICAL DEVICE

IntelliFill i.v. is a pharmacy compounding device intended to automate the production of small-volume parenteral (SVP) doses that would otherwise be prepared by hand.

IntelliFill i.v. conforms to the definition of a Class II Exempt Pharmacy Compounding Device. As such, it was designed and developed, and is manufactured and serviced, in conformance with the Quality System Regulations and is exempt from requirements for pre-market approval (as are TPN compounders and other similar pharmacy equipment).

IntelliFill i.v. is a medical device as described by the Quality System Regulations (21CFR820) promulgated by the US Food and Drug Administration (FDA). It is a Class II Exempt Pharmacy Compounding Device as described in Medical Device; Exemption from Premarket Notification;

Class II Devices; Pharmacy Compounding Systems (21CFR880) as described in the Federal Register on March 21, 2001.

INTELLIFILL i.v. AS A LAMINAR AIR FLOW HOOD

The FDA treats HEPA filters (but not laminar air flow hoods) as medical devices, but only for personal safety devices. A search of the FDA website for the term laminar air flow turned up 81 citations, all of which referred to laminar air flow as an example of drug manufacturing equipment designed to provide Class 100 (ISO Class 5) aseptic environment. Similarly, the term “isolator” produced 114 references, all of which dealt with the use of an isolator in manufacturing drugs.

Only the term “HEPA” returned documentation indicating that HEPA (high-efficiency particulate absorbing) filter units are considered medical devices. All devices cited were personal safety devices. The MAC 10 XL VE5 HEPA Fan Filter Unit (FFU) used in IntelliFill i.v. is claimed by its manufacturer to meet all applicable regulations for use in pharmaceutical processing. The FDA does not appear to regulate HEPA filters used in laminar air flow hoods.

Baxa does not claim IntelliFill i.v. to be a laminar air flow hood and laminar air flow is not a required feature of the device.

IntelliFill i.v. is manufactured for Baxa Corporation by FHT, Inc.