



New Device Approvals

Q-103 Needle Management System

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Q-103 Needle Management System
Manufacturer: QCare International, LLC
Address: 680 Atlanta Country Club Drive, Marietta, Georgia 30067
Approval Date: December 21, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p980020a.pdf>

What is it? The Q-103 Needle Management System is a device used to remove ½-inch long, 28-29-gauge hypodermic needles from insulin syringes and store them safely for later disposal.

How does it work? A needle is inserted into the opening of the device and pushed down until it stops. The device then uses battery-supplied electric current to melt off the needle. The device can hold up to 5000 removed needles.

When is it used? After an injection of insulin in order to store used needles until they can be disposed.

What will it accomplish? The Q-103 Needle Management System is intended to be used in a home care environment. The device removes and destroys the needle of insulin syringes and stores them for later disposal.

When should it not be used? The device should not be used near flammable materials or where oxygen therapy is used because it may cause explosions or fire that could result in significant injuries.

Additional information: Summary of Safety and Effectiveness and labeling are available at:
<http://www.fda.gov/cdrh/pdf/p980020.html>

Other: American Diabetes Association: <http://www.diabetes.org>