



New Device Approvals

Disintegrator™ Insulin Needle Destruction Unit - P010040

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: Disintegrator™ Insulin Needle Destruction Unit
Manufacturer: Safeguard Medical Devices, Incorporated
Address: 403 Ken Mar Industrial Parkway Unit # 475, Broadview Heights, Ohio 44147
Approval Date: March 15, 2002
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010040a.pdf>

What is it? The Disintegrator™ is a portable insulin-needle destruction device for use at home by diabetics. It uses a small 9.6 volt rechargeable battery to deliver an electrical current that disintegrates the needles. The device is intended for 27-30 gauge insulin hypodermic needles that are 5/16 to 1/2 inch in length. It can be used with most insulin pens and with disposable insulin syringes from 1/3 to 1 cubic centimeter in volume.

How does it work? The used needle is inserted into a hole on the device and the power button is pressed for a few seconds. The battery produces an arc of electricity that melts the needle tip.

When is it used? The Disintegrator™ Insulin Needle Destruction Unit is used by diabetics to dispose of needles following use.

What will it accomplish? The device destroys used insulin needles and is an alternative to puncture-resistant sharps containers.

When should it not be used? The Disintegrator™ should not be used near flammable gases or liquids.

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p010040.html>

Others:

- National Institutes of Health (NIH): Easy to Read Diabetes Information:
<http://www.niddk.nih.gov/health/diabetes/dy1b/chap6.htm>
- Los Angeles Times Comprehensive Feature on Diabetes
<http://www.latimes.com/features/health/la-000088381nov05.story>
- American Diabetes Association: General Information <http://www.diabetes.org/main/info/link.jsp>
- American Diabetes Association Information on Needles:

<http://www.diabetes.org/diabetesforecast/2001BuyersGuide/page52.asp>

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