SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Sharps Needle Destruction Device for Insulin Needles

Device Trade Name: The Disintegrator™ Insulin Needle Destruction Unit

Applicant's Name and Address:

Mr. Joey Adkins
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Premarket Approval (PMA) Application number: P010040

Date of Notice of Approval to the Applicant: March 15, 2002

II. INDICATIONS FOR USE

The Disintegrator™ is an insulin needle destruction unit for home use. It is a sharps needle destruction device that is designed to incinerate 27-30 gauge insulin needles, 5/16 to ½ inch in length, attached to insulin pens and disposable insulin syringes of 1/3cc to 1cc volume sizes.

III. CONTRAINDICATIONS

There are no known contraindications for the use of this device.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the attached instruction sheet and device labeling for the Disintegrator™.

V. DEVICE DESCRIPTION

The Disintegrator™ is a home use, portable sharps needle destruction device for diabetics. It uses electrical current to incinerate 27-30 gauge insulin hypodermic needles 5/16 to 1/2 inch in length attached to insulin pens and disposable insulin syringes of 1/3 cc to 1 cc volume in size. The Disintegrator uses a rechargeable 9.6-volt battery to deliver an electrical current to produce an arc of electricity directed at the tip of the needle. This arc of electricity melts the tip of the needle and disintegrates the needle. Any balls of melted metal that fall off during the process are collected into a chamber where the ash or ball is sealed and does not

need to be emptied. The remaining stub of the needle on the hub is less than 1/16th inch in length. The device also includes a small molded port at the top, which is a needle straightener, for use in straightening needles that are bent prior to destruction.

The Disintegrator™ uses a large button as the switch to turn on the device and activate the circuit that supplies the charge. There is a low battery charge light that is yellow, which is found at the top of the device. Before first use, the Disintegrator battery should be charged for 12 hours. A fully charged battery is indicated by a green light located next to the yellow light. When the green light is lit this device will disintegrate 30-40 needles before needing to recharge. The Disintegrator™ unit can be powered from a battery and/or AC current by a wall transformer. The battery can be recharged by the wall transformer within 45 to 90 minutes. The Disintegrator™ can be utilized when the battery is recharging. The device exterior surface is off-white PC/ ABS (flame-retardant) Resin with a blue needle port. The tear shaped Disintegrator™ measures 6"X4"X 2" and weighs 2 pounds. The Disintegrator™ is to be used in closed proximity to the site of needle use.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative disposal methods of insulin syringes and pen needles include placement in a sealed puncture proof container prior to discarding in the trash or transporting to a sharps collection center; or use of another commercially available needle destruction device.

VII. MARKETING HISTORY

The Disintegrator ™Insulin Needle Destruction Unit was introduced into Canada in June of 2001. Approximately 150 units are currently in use with no report of any customer complaints. The Disintegrator ™Insulin Needle Destruction Unit has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

There are no anticipated adverse effects on patient health from the use of The Disintegrator™. No adverse effects were reported during the clinical studies. Failure of the device to destroy the needle subjects the user to no greater risk than would be encountered with no use of a destruction device. Failure of the device to fully destroy the needle still results in a blunted and completely sealed needle tip.

IX. SUMMARY OF NON-CLINICAL STUDIES

Mechanical / Positional Stability

The device is supported with raised legs along the outer perimeter of the bottom, resulting in extreme stability during use. Tests were performed to determine whether the unit could be made to tip over by activating the "button" from various angles.

Results: The device remained stable during all tests.

Conclusion: The results of stability testing indicate that The Disintegrator™ is not prone to tipping during use.

Structural Integrity

Independent laboratory tests were performed to test the structural strength of The Disintegrator™ according to standards outlined in UL-2601.

Results: The device passed all tests.

Conclusion: The housing strength of the device is acceptable.

Ergonomic Considerations

The Disintegrator™ is designed with the needle port, needle straightening aid, and actuator button all on centerline. The indicators are equidistant from center and are visible from a wide viewing angle of approximately 120 degrees. In-house tests were conducted with both left and right-handed individuals to determine comparative ease of use.

Results: The device was found equally usable by both left and right handed individuals.

The prospective clinical study protocols required representation of both left-handed and right handed patients.

Results: There were no reports of difficulty in use attributable to the patient being left or right handed.

Conclusion: The Disintegrator™ may be used with equal efficiency and effectiveness by either left or right handed individuals.

Generation of Noise

Measurement of noise during the destruction cycle was taken at a distance of 18 inches from the device.

Results: The increase in noise level during destruction was less than 3 dB, the minimum change normally detectable by the human ear.

Conclusion: The device poses no potential of excess noise generation.

Generation of Heat

The temperature of the case at the port entry was monitored during the destruction of 10 needles over a 10 minute period (much more rapid than anticipated for a single insulin user).

Result: A total temperature rise of less than 5 degrees F was measured.

Independent laboratory tests were performed to determine the temperature rise on various internal components during both normal and intentional misuse, as well as in specific "failure" modes, according to safety standards outlined in UL-2601.

Results: All tested components had a temperature rise within the limits of the UL-2601 standard.

Conclusion: Neither external nor internal temperature rise during the needle destruction process poses a threat to the user.

Formation of Sparks

During the in-house destruction of over 4,000 needles to date, no notice was made of any sparks generated outside the unit. Although reports of visible sparks inside the unit were recorded by some of the Study Subjects involved in the Clinical Trials, there were no reports of visible external sparks.

Results: There were no visible sparks generated outside the unit during destruction.

Conclusion: As no sparks were visible outside the unit, it is concluded that no direct user hazard exists from sparks. However, it is known that the device uses an internal low-powered electric arc to dispose of the metal needle body. For this reason, the unit should not be used near flammable gases or liquids. The Disintegrator™ is labeled accordingly.

Electrical Shock Hazard and Electromagnetic Compatibility

The Disintegrator™ is powered with a rechargeable 9.6 volt Ni-Cad battery incapable of shock hazard. The device is designed to prevent operation in the event that the case or battery / ash door has been opened. The AC adapter selected for recharging the battery is an off-the-shelf sealed unit listed under both UL and CSA standards.

An independent laboratory study was conducted to evaluate the electrical safety of The Disintegrator™ according to UL 2601-1 (1997 edition).

Results: The unit passed all applicable requirements for electrical safety.

Additional laboratory testing of EMC levels was performed to EN-55011 standards. Tests were performed on a "Disintegrator" unit that contained no added shielding for EMI, as manufactured for the consumer market. Tests were also performed on a unit with shielding added in the form of EMI conductive paint, as might be the case for "Disintegrator" units intended for U.S. clinical sales.

Results: The unshielded unit showed short peaks of some radiated signals slightly above the limits of EN-55011. Modifications were made to the unit in the form of EMI conductive paint on the internal walls. This unit showed reductions in all radiated emissions to well below the limits of EN-55011.

Conclusions: Electrical safety and EMI test results are acceptable for the device as intended for use by consumers. EMI test results show that units intended for use in U.S. clinical settings would need to be manufactured utilizing EMI shielding materials.

Emission of Toxic Fumes

The Disintegrator™ was tested during operation to identify and qualify airborne contaminates potentially generated by destruction of ten 27 gauge needles 1/2 inch in length. The test was designed to analyze the components of the needles based on their potential to cause deleterious health effects. These components were determined to be chromium, nickel, manganese and iron. An airtight chamber with a sampling pump was constructed to collect and filter air samples during operation of the unit. Three trials were performed with 10 syringes, each equipped with a ½ inch by 27 gauge needle, were tested over a 10 minute period per trial and the mass of each of these elements found in the filtered air was measured using a Perkin Elmer Sciex, Elan 5000, ICP / Mass Spec system. The concentration of the materials found in the sampled air were determined, by extrapolation, to be 256 times the concentration level which would have been found in 1 cubic meter of air.

Results: The levels found in the concentrated air were found to be less than 0.002 (0.2%) of the safe limits established by the EPA. If the samples had in fact been taken from a 1 cubic meter enclosure, the concentration levels would have been below detection limits.

Conclusions: The concentrations of these metals or their oxides that are emitted from use of The Disintegrator™ represent an unusual use of the device but are within safe limits.

Formation of Infectious Aerosols

A Disintegrator™ device was sent to U.S. Micro-Solutions, Inc. of Greensburg, PA for testing to determine the potential for the formation of infectious aerosols generated from use of the unit. An Anderson N-6 Single Stage Air Sampler was placed next to the Disintegrator™ inside a Class II Biological Safety Cabinet, with a TSA plate placed into the sampler and 4 TSA plates placed around the unit. A total of 20 sterile insulin needles were destroyed and the plates incubated at 35 degrees (C) for 48 hours. This process was then repeated using 20 insulin needles contaminated with a 1 to 5 x 10^5 suspension of *Bacillus subtilis.* A TSA plate inoculated with the suspension of *Bacillus subtilis* bacteria was used as the Positive Control. The air inside the biosafety cabinet was sampled with the N-6 Sampler, before destruction of any needles, and used as the Negative Control.

Results: All trypticase soy agar (TSA) plates had no growth of *Bacillus subtilis* except for the Positive Control plate.

Conclusion: The Disintegrator™ does not appear to generate an infectious aerosol during its use.

Ability to Completely Destroy the Needle

Simulated laboratory tests were performed on more than 4,000 insulin needles, ranging from 27 to 30 gauge and lengths of 5/16 and ½ inch long, attached to syringes ranging in dosage from 3/10cc to 1cc. Insulin pens were also similarly tested. The study evaluated adequate destruction if the remaining "stub" was less than 1/16 inch long, whether or not terminated by a small BB shaped ball.

Results: All needle sizes and gauges were adequately destroyed.

The prospective clinical studies also evaluated actual needle destruction by insulin users in the home. In these studies the destruction criteria remained the same as in the laboratory setting.

Results: In the clinical studies the worst case rate of successful needle destruction was at least 93.3%.

Conclusion: The Disintegrator™ successfully demonstrated needle destruction for 27-30 gauge insulin needles in 5/16 and ½ inch lengths. Additional labeling instructions clarifying the battery charging requirements were added for the second clinical study, and are now added to all devices produced. This should help to maintain a high percentage of successful needle destruction.

X. SUMMARY OF CLINICAL STUDIES

The objective of the clinical studies was to determine the effectiveness of The Disintegrator when used in the home by a variety of patients who inject insulin, following only the directions supplied by the manufacturer.

Study Design

The assessment of safe use and the effectiveness of needle destruction was based on:

1) Patients' ability to properly follow written instructions provided with the device;
2) Destruction of the needle body to a "stub" of 1/16 inch or less in length;
3) The number of adverse device events; and
4) User comments regarding the use of the device.

During the clinical studies a total of 18 patients were enrolled for a 30-day study period. Patient selection criteria were based on a mixture of patients across a wide age range, both left and right handed, who inject insulin a minimum of 2 times per day. In addition, at least one patient was selected who suffered from some degree of diabetes induced visual impairment. Fourteen patients provided documentation demonstrating completion of all tests. The patients used an adjusted total of 905 needles. Included in the total number of needles are 169 "test syringes" representing 4 different syringe manufacturers and 11 different gauge and size combinations. These "test syringes" were supplied to the patients in their test kits. The study was approved by an IRB associated with the Cleveland Clinic where the patients were obtained. The tests took place in the patient's home.

Results

Of the 905 needles tested, there were 42 reports of unsuccessful needle destruction. Of these failures, the study subjects documented 12 as attributable to their failure to recharge the battery, and another 7 were reported as due to improper use of the device inserts. The remaining 23 failures are attributed to imperfect mechanism operation, which could occur due to the manufacturing process used for the clinical trial production units. The firm has addressed the

issue of improper battery charging by revisions in the device labeling. The issue of mechanical imperfections is self-resolving in that all future production of mechanical components will utilize final injection molding with much tighter tolerances. There were no adverse events reported during the clinical study.

Conclusion

The device safely and successfully destroys 27-30 gauge insulin needles when used as directed in the instructions for use.

XI. SUMMARY CONCLUSIONS DRAWN FROM THE STUDIES

The pre-clinical and clinical testing provides reasonable assurance of the safety and effectiveness of the Disintegrator ™Insulin Needle Destruction Unit device when used in accordance with the manufacturers' instructions for use.

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the General Hospital and Personal Uses Devices Advisory Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

The applicant's manufacturing facility was inspected on January 18, 2002 and was found to be in compliance with the Quality Systems Regulations. FDA issued an approval order on March 15, 2002.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the attached labeling.

Hazards to Health from Use of the Device: See Contraindications, Warnings, Precautions and Adverse Reactions in the attached labeling.

Post-Approval Requirements and Restrictions: See approval order.