

K970737

SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 28 1997

1.0 Submitted By:

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2.0 Device Name:

B-D 31g x 5/16" pen needle

3.0 Predicate Device:

B-D 30g x 5/16" pen needle

4.0 Device Description:

The double-pointed Type 304 stainless steel needle is epoxy bonded to a plastic hub (polypropylene) and covered with a plastic needle shield (polyethylene). This needle/hub/shield assembly is placed in a plastic outer container (polyethylene), the open end of which is sealed closed with a laminate seal for subsequent protection. Gamma irradiation sterilization will be employed and the product will meet 10^{-6} sterility assurance levels. During use, the laminate seal is peeled away and the exposed needle hub is screwed onto the Pen injector device. This exposed needle hub will penetrate the rubber septum of an insulin containing cartridge (supplied by others). After the needle shield is removed, it is ready for a subcutaneous insulin injection. The needle assembly is a single-use disposable device.

5. Intended Use:

The intended use for the modified device remains the same as the predicate device; for use with a pen injector device for the subcutaneous injection of insulin.

6. Technological Characteristics:

The B-D 31g x 5/16" pen needle and the predicate device (the B-D 30g x 5/16" pen needle) have the same technological characteristics.

SEE ITEM 4 ABOVE FOR A DESCRIPTION.

N.B. The only change to the predicate device is the gauge size of the needle.

7. Performance Summary:

The B-D 31g x 5/16" pen needle has been bench tested, which included needle pull-out, penetration and insulin injection forces and has proven to function in an equivalent manner as the predicate device.

Based on the results of bench testing the B-D 31g x 5/16" pen needle is considered safe and effective when used as intended.