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K953940

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510(k) SUMMARY

Name of the Device:

Terumo Retractable Needle (RN) Syringe

Predicate Product(s):

There are two products referenced as predicates for the Terumo RN Syringe:
- Terumo Hypodermic Syringes with Needles, K771205 and K771203.
- U.S. Medical Instruments SafeSnap™ syringe, K925039.

Description of the Subject Device:

The Terumo RN Syringe is a sterile, single use device designed to be similar to present single use products. A needle retraction feature allows the user to withdraw the needle into the barrel of the syringe immediately after use.

Intended Use of the Device:

The intended use of the Terumo Medical Corporation (Terumo) RN Syringe is to inject fluids into, or withdraw fluids from, the body below the surface of the skin for medical purposes.

Comparison of Subject Device to Predicate Device(s):

The Terumo RN Syringe is similar in design, feel and function to a standard Terumo hypodermic syringe with needle. This syringe provides the user with a product similar to a standard disposable syringe that will require little, or no change in the technique that is presently used.

The materials in the subject device are the same as Terumo's standard hypodermic syringe and needle with the exception of the addition of an "O" ring made of silicone. These materials have been tested and as a part of the whole product biocompatibility testing in accordance with the current CDRH guidance.

The needle retraction mechanism of the Terumo RN Syringe locks the needle hub with an adapter on the distal end of the plunger after injection, and allows the needle to be withdrawn into the barrel of the syringe. The predicate syringe requires the user to ensure that the plunger rod has locked into the needle carrier and then to disengage an external locking ring after the completion of the injection. The withdrawal of the plunger rod retracts the needle within the barrel of the syringe. The user then snaps off the plunger rod and inserts the broken segment of the rod into the open end of the barrel and, disposes of the unit in an appropriate sharps container. The needle retraction mechanism of the Terumo RN Syringe is similar to that of the predicate product, except there is no need to disengage a locking ring. The retraction feature of both devices prevents the accidental reuse of the device.

Safety Information:

- The Terumo RN Syringe is sterilized by gamma radiation to provide a Sterility Assurance Level (SAL) of 10^{-6} .
- Blood or fluid contacting materials were tested as the whole device for biocompatibility using the FDA's modification of the ISO 10993 Standard as an external communicating device; blood path, indirect; short term exposure and found to be biocompatible.
- The product was found pyrogen free when tested in accordance with U.S.P. XXIII.
- Shelf life for the RN Syringe is based on our experience with Terumo's standard syringes. An additional accelerated test program will be intended that will confirm the full dating period.

Performance Data:

Discussion of Non-Clinical Tests

The non-clinical tests performed on the Terumo RN Syringe are the same protocols and standards used for the evaluation of our standard syringe products. In addition the needle retraction feature was tested with a lock - out and drop test to assure that the needle would remain retracted within the barrel of the device.

Discussion of Clinical Tests

An analysis of the similarities in design, materials, use and function of the Terumo RN Syringe with the predicate products, establishes that the need for simulated clinical use and actual clinical use testing is unnecessary.

Conclusions Drawn from Testing

Since the device is similar to current single use syringes and the needle retraction function is essentially equivalent to the predicate product, there are no new issues of safety or effectiveness involved in the use of the Terumo RN Syringe.

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TMC's statement that these devices are substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug, and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Submitter's Information:

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