510(k) Summary: Nipro Syringe

807.92(a)(1)

Applicant: Nipro Medical Corporation
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Date of summary preparation: March 29, 2018

807.92(a)(2)

Trade Name: Nipro Syringe
Common Name: Disposable syringe with or without Needle
Classification Name: piston syringe
Regulation Number: 880.5860
Regulatory Class: II
Panel: General Hospital (80)
Product Code: FMF

807.92(a)(3)

Legally marketed substantial equivalent device:
Nipro Branded Disposable Syringes, Needles - K944355

807.92(a)(4)

Description of device:
The NIPRO Syringe is a piston syringe consisting of graduated barrel, plunger rod, and gasket. It is provided in luer slip, luer lock and eccentric luer slip tips, with and without attached hypodermic needles. Needles are available in ranges of 20-25G, and 3/8 to 1 ½" in length. Gauges are color coded for easy differentiation. Its function is mechanical. The syringe is sterile, single use only, non-toxic, non-pyrogenic and sterilized by Ebeam radiation. The shelf-life has been determined to be 5 years. This device is not intended for patients less than 2 years of age.

807.92(a)(5)

Indications for Use: to inject fluids into or withdraw fluids from the body

807.92(a)(6)

Comparison of technological characteristics:

The syringe is substantially equivalent to the predicate device in the following technological characteristics:

Element of Comparison	Subject device	Predicate device
Materials	• Polypropylene – different grade than predicate to accommodate Ebeam sterilization. • Elastomer • Stainless steel	Same
Design: Operational mode	Mechanical	Same
Design: Physical characteristics	• Hollow graduated barrel • Plunger rod • gasket	Same components; dimensions slightly different than subject device
Design: Device Configurations	• Luer lock • Luer slip • Eccentric tip • With needle • Without needle	Same
Intended Use	to inject fluids into or withdraw fluids from the body	Same
Sterilization Method	Ebeam Radiation	Ethylene Oxide gas
Expiry dating	5 years	Same
Energy Source	NA	same

Table 4: Comparison of technological characteristics

807.92(b)(1)

Non-clinical tests submitted are outlined below. All of these tests were performed within the specifications of the standards listed.

1. Visual Inspection (ISO 7886-1, ISO 7864-1)
2. Dimensional Specifications (ISO 7886-1)
3. Gauging (ISO 594-1)
4. Mechanical and Performance Characteristic (ISO 7886-1, ISO 7864-1, ISO 594-1, ISO 594-2)
5. Chemical and biological characteristic (ISO 7886-1, ISO 11137-1)
6. Sterilization validation (ISO 11137-1, ISO 11137-2, ISO 11137-3)
7. Transportation tests (ASTM-D4169-09)

8. Biocompatibility (ISO 10993)
    a. Cytotoxicity: MEM Elution
    b. Sensitization: Kligman Maximization
    c. Intracutaneous Irritation
    d. ISO Systemic Toxicity Study in Mice
    e. USP Rabbit Pyrogen Study, Material Mediated
    f. ASTM Hemolysis Study
    g. USP Limulus Amebocyte Lysate (LAL) testing, Kinetic-Chromogenic Method
    h. Particulate Analysis – Device fluid pathway
9. Pyrogen testing (ISO 10993-11, USP 39-NF34: 2016, <151>)
10. Shelf-life testing (ASTM F1980-07)

807.92(b)(2)

This submission does not warrant any clinical testing, therefore no clinical testing performed for or provided in this submission.

807.92(b)(3)

Conclusions drawn from non-clinical and clinical tests:

There are no differences in fundamental scientific technology and operational mode.

There are non-significant differences in materials and physical specifications.
The material change is due to the predicate materials not being able to withstand Ebeam sterilization and although there are slight dimensional changes the predicate and the subject device both remain in compliance with all aspects of ISO 7886-1 substantiating the claim of equivalence.

The results of the performance testing and the comparison of technological characteristics with the predicate device demonstrate that the Nipro Syringe with and without Needle performs equivalent to the predicate device when used as intended.