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510(k) Summary

This summary regarding 510(k) safety and effectiveness and being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

**§ 807.92 (a)(1) Submitter's (and Contact) Names, Address, Telephone No., Summary Date**

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**§ 807.92 (a)(2) Device Name (Including Trade Name), Common Name, Classification Name**

- MX531-1LT Antimicrobial IV Set Stopcock and MX491T Antimicrobial Luer Lock Plug
- Stopcock and Luer Lock Plug
- Stopcock, I-V Set

**§ 807.92 (a)(3) Legally Marketed Predicate Device to Which Equivalence is Claimed**

- Medex, Inc.'s pre-amendment stopcock and Luer lock plug MX531-1L and MX491, respectively.
- Additionally, the modified devices use a substantially equivalent technology as the Vitaphore Corporation's VitaGuard® Percutaneous Infection Control Kit (K861563).

**§ 807.92 (a)(4) Description of the Premarket Notification Device**

- The Medex, Inc. antimicrobial stopcock and Luer lock plug are functionally conventional devices, which incorporate antimicrobial properties through the addition of a elemental, metallic silver additive.
- The materials which comprise the MX531-1LT and MX491T have been aggressively tested per the ANSI/AAMI/ISO 10993 "Biological Evaluation of Medical Devices" and the "Tripartite Biocompatibility Guidance for Medical Devices". All materials have successfully met these standards.

**§ 807.92 (a)(5) Intended Use**

- A stopcock is a typical element of fluid or drug administration. It is used to control/direct fluid flow and permit fluid access to the patient. A Luer lock plug is used to terminate any open Luer port.

- The silver antimicrobial additive will enhance performance by minimizing the possibility the devices will be microbially compromised.

### **§ 807.92 (a)(6) Technical Characteristics Summary**

#### **Similarities:**

- The base function of the MX531-1LT and the MX491T are identical to the respective pre-amendment MX531-1L and MX491 devices. The MX531-1LT and the MX531-1L are three-way stopcocks to be used to control/direct fluid flow and permit fluid access to the patient. The MX491T and the MX491 are Luer lock plugs designed to close open or exposed Luer ports.
- The antimicrobial component of the MX531-1LT and the MX491T is technologically similar to the antimicrobial component of the VitaGuard. Both use elemental silver to enhance the performance of the device by reducing the possibility of it becoming contaminated by microorganisms.
- The base material of the MX531-1LT and the MX531-1L are identical: polycarbonate, HDPE, and acrylic.
- The base material of the MX491 and the MX491T are identical: HDPE.
- The fluid path of both the MX531-1LT and the MX531-1L are clear to aid in visualization of the path during priming and use.

#### **Differences:**

- The MX531-1L does not incorporate any kind of antimicrobial component, the MX531-1LT incorporates a elemental, metallic silver antimicrobial.
  - The silver antimicrobial is intended to enhance the performance of the MX531-1LT stopcock by reducing the possibility of becoming contaminated by microorganisms.
- The MX491 does not incorporate any kind of antimicrobial component, the MX491T incorporates a elemental, metallic silver antimicrobial.
  - The silver antimicrobial is intended to enhance the performance of the MX491T Luer lock plug by reducing the possibility of it becoming contaminated by microorganisms.
- The MX531-1LT and the MX491T meet the most current biocompatibility standards: ANSI/AAMI/ISO 10993.
  - The MX531-1L and the MX491 meet USP XXIII requirements.
- The silver antimicrobial component of the MX531-1LT and the MX491T is designed **not** to be soluble (0.000000024 g/8 h or 2 µg/4 weeks).
  - The collagen of the VitaGuard is designed to dissolve with use constantly releasing its silver component (14 µg /4 weeks).

### **§ 807.92 (b)(1), (b)(3) Performance Testing Assessment**

To assess the antimicrobial efficacy of the modified devices, a large masked *in vitro* study was completed. The protocol was designed to closely emulate clinical use for the stopcock with Luer lock plug. The study addressed the difference in the amount of recoverable microbes between the antimicrobial devices and their non-antimicrobial counterparts under the following treatments (200 units divided into four groups):

- i. The devices were contaminated every twenty-four (24) hours and sampled every eight (8) hours over a seventy-two (72) hour period.
- ii. The devices were contaminated every twenty-four (24) hours and sampled every twenty-four (24) hours over a seventy-two (72) hour period.
- iii. The devices were contaminated one time and sampled every eight (8) hours over a seventy-two (72) hour period.
- iv. The devices were contaminated one time and sampled every twenty-four (24) hours over a seventy-two (72) hour period.

The device fluid paths were inoculated as indicated with a cocktail containing  $1.2 \times 10^4$  total microorganisms of the following:

- *Staphylococcus aureus* (ATCC #6538)
- *Pseudomonas aeruginosa* (ATCC #9027)
- *Escherichia coli* (ATCC #8739)
- *Candida albicans* (ATCC #10231)
- *Streptococcus pneumoniae* (ATCC # 49136)
- *Staphylococcus epidermidis* (ATCC #12228)
- *Klebsiella pneumoniae* (ATCC #13882)
- *Bacillus subtilis* (ATCC #6633)

In all cases, the difference between the number of bacterial CFU's (colony forming units) recovered from the antimicrobial and the non-antimicrobial stopcocks and Luer lock plugs was extremely statistically significant. The median CFU count at every sampling time in all groups was consistently lower for the antimicrobial devices compared to the standard non-antimicrobial devices. The antimicrobial devices showed from 43% to 99% less microbial contamination between eight and seventy-two hours of use. When compared to the inoculum level (i.e.  $1.2 \times 10^4$ ), the antimicrobial devices showed from a 28% to 99% functional reduction in the microbial level.