SPS medical
Sterilization Monitoring • Packaging • Testing Services

ORIGINAL

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CYTOTOXICITY TEST REPORT

Client: Healthmark Industries
33671 Doreka Dr.
Fraser, MI 48026

Phone: 800-521-6682

Study No.: SPS-0910-347

Test No.: 133843 & 133843-2
133844 & 133844-2

Samples: Count Sheets with 100% ink coverage
Healthmark Paper Bag

Received: 11/4/09

Procedure: A tray was fully loaded with medical instruments and simulated medical instruments along with two (2) SPSmedical STEAM*Plus*™ Class 5 sterilization integrators. The total combined weight of the tray was 25 lbs. Three (3) count sheets (printer: HP 930c, Ink: 45 HP inkjet cartridge) were tri-folded (letter style) and placed inside a Healthmark paper bag on top of the load in the tray. The tray was wrapped with KC400 using the simultaneous envelope fold. The wrapped tray was then sterilized using the parameters provided by the Client (pre-vacuum steam at 270°F for 4 minute exposure, and 20 minutes dry time). After processing, the sterilization parameters were verified with printouts and the Class 5 integrators. The count sheets and paper bag were removed and tested separately using a MEM Elution Cytotoxicity Assay per USP and ISO methods.

Criteria: The MEM Elution test system is valid if the observed responses to the negative control maintains a healthy normal appearance throughout the duration of the test and the positive control scores a grade of 3 (moderate) or 4 (severe). The Test Samples meet the requirements of the test if the response is not greater than grade 2 (mild).

If the suitability of the test cannot be confirmed then the test may be repeated.

Reactivity grading system: **0** = none, **1** = slight, **2** = mild, **3** = moderate, **4** = severe

Results: The test Samples scored a grade of **0** indicating no reactivity. Positive controls scored a grade of **4** and negative controls scored a grade of **0**.

Conclusion: The test Samples meet the USP and ISO 10993-5 requirements for this test. All controls were acceptable and the test considered valid. The test sample PASSES and is considered NON-TOXIC under the test conditions employed.

References: Association for the Advancement of Medical Instrumentation Standards and Recommended Practices, 2000 Edition, Volume 4S2, Supplement 2: Biological Evaluation of Medical Devices-Part 5: Test for Cytotoxicity: In Vitro Methods (Identical to ISO 10993-5:1999)

Current Edition - United States Pharmacopeia/National Formulary, <87> Biological Reactivity Test, In Vitro; Elution Test

Test report prepared by: Alex Bahl Date: 3/24/10

Test results reviewed by: Don Jensen Date: 3/24/10