K955594

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ATTACHMENT 8

510(k) Summary

K955594

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510(k) Summary

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

"The assigned 510(k) number is: _____."

1) Submitter Information

McGaw, Inc.
2525 McGaw Avenue
P.O. Box 19791
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Contact Person: John G. D'Angelo, M.S., R.Ph.
Director, Regulatory Affairs
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2) Name of Device

Trade/Proprietary Name: SafeLine™ I.V. Bag Access Device
Common/Usual Name: I.V. Fluid Transfer Set
Classification Name: Set, Intravascular, Administration

3) Predicate Device

The currently marketed McGaw SafeLine Injection Site is the predicate device used for the substantial equivalence claim

4) Description of the Subject Device

The SafeLine™ I.V. Bag Access Device is an additional accessory device for use with McGaw's SafeLine System. It is a single sterile plastic device composed of a pre-slit rubber septum injection site, a standard I.V. bag spike and a spike protector. The SafeLine I.V. Bag Access Device is designed to withdraw drugs from standard size I.V. bags through a blunt plastic cannula attached to a syringe. Thus providing needlefree access of IV bags. As with all of the currently marketed SafeLine devices, the new SafeLine I.V. Bag Access Device is tinted green to signify a needle free SafeLine product.

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5) Intended Use of the Subject Device

The SafeLine I.V. Bag Access Device is intended for multiple withdrawals of fluid from the set port of standard I.V. bags. The spike portion of the SafeLine I.V. Bag Access Device is inserted into the I.V. bag set port and the fluid is withdrawn using a blunt plastic cannula connected to a syringe. The fluid is withdrawn into the syringe through the blunt plastic cannula inserted into the injection site portion of the SafeLine I.V. Bag Access Device. The fluid in the syringe can then be used for performing "I.V. pushes," to flush patient I.V. lines, or other pharmaceutical uses. The SafeLine I.V. Bag Access Device replaces the use of a traditional metal hypodermic needle to provide needlefree access to I.V. Bags. Thus, eliminating the potential for accidental needlestick injury.

6) Technological Characteristics of the Subject Device

The subject device, the new SafeLine™ I.V. Bag Access Device, is substantially equivalent to the predicate device, the currently marketed SafeLine Injection Site. There are technological differences between the subject device and the predicate device. However, these technological differences do not raise any different questions of safety and efficacy. The substantial equivalence statement is supported by the information presented in this 510(k) submission. This information is contained in Attachments 1 through 7 and includes the following:

- Description and intended use of the subject device and the predicate device
- Comparison of the attributes of the subject device with the attributes of the predicate device
- Drawing of the subject device
- Biocompatibility testing of the subject device materials
- Functional performance testing of the subject device and comparison testing of the subject device with a standard I.V. bag spike
- Microbiological challenge testing of the subject device
- Draft labeling of the subject device and the predicate device current labeling

The conclusions drawn from the information listed above support that the new SafeLine I.V. Bag Access Device is substantially equivalent to the currently marketed SafeLine Injection Site.

7. Signature of Applicant:

McGaw, Inc.
John G. D'Angelo, M.S., R.Ph.
Director
Regulatory Affairs

Diane Hurst for J. D'Angelo
Signature

12-7-95
Date