MAR - 6 1996

K955595

ATTACHMENT 7

510(k) Summary

McGaw, Inc.
2525 McGaw Avenue
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Irvine, California 92713-9791
Telephone: 714.660.2000
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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: K955595 *."*

1) Submitter Information

McGaw, Inc.
2525 McGaw Avenue
P.O. Box 19791
Irvine, California 92713-9791

Contact Person: John G. D'Angelo, M.S., R.Ph.
Director, Regulatory Affairs
Phone: (714) 660-2517
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2) Name of Device

Trade/Proprietary Name: SafeLine™ Multidose Vial Adapter
Common/Usual Name: I.V. Fluid Transfer Set
Classification Name: Set, Intravascular, Administration

3) Predicate Device

The currently marketed Baxter InterLink® System Universal Vial Adapter is the predicate used for the substantial equivalence claim.

4) Description of the Subject Device

The SafeLine™ Multidose Vial Adapter 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 drug vial spike and a plastic spike tip protector. The SafeLine Multidose Vial Adapter is designed to withdraw drug solution from the solid stopper of standard size drug vials using a blunt plastic cannula attached to a syringe. Thus providing needlefree access of drug vials. As with all of the currently marketed SafeLine devices, the new SafeLine Multidose Vial Adapter is tinted green to signify a needle free SafeLine product.

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5) Intended Use of the Subject Device

The SafeLine Multidose Vial Adapter is intended for multiple withdrawals of drug solution from standard size drug vial solid stoppers. The spike portion of the SafeLine Multidose Vial Adapter is inserted into the drug vial solid stopper and the drug solution is withdrawn using a blunt plastic cannula connected to a syringe. The fluid is withdrawn into the syringe through the blunt plastic cannula inserted into the injection site portion of the SafeLine Multidose Vial Adapter. The drug solution in the syringe can then be transferred to an I.V. administration set with a pre-slit septum injection site for administration of the drug solution to the patient. The SafeLine Multidose Vial Adapter replaces use of a traditional metal hypodermic needle to provide needlefree access to drug vials. Thus, eliminating the potential for accidental needlestick injury.

6) Technological Characteristics of the Subject Device

The subject device, the SafeLine™ Multidose Vial Adapter, is substantially equivalent to the predicate device, the Baxter InterLink® System Universal Vial Adapter. 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 claim is supported by the information presented in this 510(k) submission. This information is contained in Attachments 1 through 6 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
- Material composition of the subject device components
- Drawing of the subject device
- Functional performance and comparison testing of the subject device and the predicate device
- Microbiological challenge testing comparing the subject device and the predicate 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 Multidose Vial Adapter is substantially equivalent to the Baxter InterLink System Universal Vial Adapter.

7) Signature of Applicant:

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

Diane Grant for J D'Angelo

Signature

12-7-95

Date