

510(k) SUMMARY OF SAFETY and EFFECTIVENESS

AUG - 1 1996

Date of Summary: May 8, 1996

Submitter's name: Merit Medical Systems, Inc.
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Contact Person: Dennis (Dan) Reigle

Name of device: Contrast Management System

Class: Class II

Classification name: Intravascular Administration Set

Predicate device: The predicate device is the "contrast savings delivery system" manufactured by North American Instrument Company (NAMIC®) and reviewed by FDA under premarket notification number K903493.

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DEVICE DESCRIPTION

The device consists of two parts; the spike assembly and the Miser™ fluid administration set. The spike assembly is inserted into a container of contrast media. The Miser is then attached to the spike assembly. The distal end (fixed male luer) of the Miser is attached to a manifold port (or stopcock with syringe). The stopcock on the spike assembly is opened to allow the contrast to flow into the Miser's burette chamber. The burette is filled to approximately the 10 ml level and then the contrast flow stopped by closing the stopcock on top of the burette. As contrast is withdrawn from the Miser, the level within the burette will remain at approximately the same level until the contrast in the container is depleted. The shut-off disc within the burette prevents air from entering the system when the contrast container becomes empty. The stopcock below the burette may be opened to allow the contrast contained within the proximal tubing to be aspirated.

The contrast manager is attached to a manifold port or a three way stopcock. A control syringe is connected to the manifold or stopcock on the opposite side from the indwelling catheter. Opening the port between the contrast manager and the syringe allows the syringe to aspirate contrast media. The port between the syringe and catheter is opened and the contrast can be injected into the catheter. This process can be repeated until the contrast is expended.

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Safety Considerations

The components in the fluid administration set have been used for four years with various types of contrast media (ionic and non-ionic) without overt problems.

The redundant one way check valves were challenged to verify a high degree of reliability that retrograde flow is not possible through the one way valves thus preventing patient cross contamination.

An arbitrary six hour time limit was imposed by the predicate device manufacturer for the spike assembly to remain connected to the container of contrast. Merit agrees with this time limit and has indicated this limitation in the Instructions for Use. Merit used the six hour time limit as the exposure time for challenging the one way check valves.

The protective dust cap (that is placed on the spike assembly between cases) is packaged in a separate pouch thereby preserving its sterility until needed.

Air filters are connected to all ports where air may be drawn into the system thereby preventing contamination from airborne contaminants. The air filter was challenged to verify its ability to effectively filter a test aerosol.

The Medical Device Reporting database was searched for MDRs from the two predicate device manufacturers for events relating to contrast infusion sets.

Although there were no reports directly naming the predicate devices, there were several related reports. The events reported either air leaking into the infusion set or contrast leaking out. To prevent tubing set leaks, Merit has incorporated a final leak test for all (100%) tubing sets to verify set integrity. In addition, a cautionary statement is included in the labeling to verify connection integrity before use.

A study has shown radiological contrast agents to have anti-bacterial (bactericidal or bacteristatic) activity.

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