

K961752

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510(k) Summary

A. REQUIRED INFORMATION

1. Submitted by
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1895,
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2. Device name
Modified Hysterosalpingography Set
3. Predicate Device
Modified Hysterosalpingography Set - K953034
4. Description of the device (See Exhibit 2)
The Modified Hysterosalpingography Set consists of three
parts: a double-lumen, balloon bearing catheter; a semi-
rigid placement sheath, and a syringe to inflate the
balloon.

The double-lumen catheter will be available in two diameters, 5F and 7F, and is composed of a radiopaque flexible plastic tube 30cm. long. The distal end will have either a side port or end port. The balloon which is composed of a synthetic elastomer of a natural, clear polyurethane material is mounted 5 to 8 mm proximal to the distal end. The proximal end of the catheter is composed of a fitting leading to a bifurcation; one extension is for balloon inflation, the other for contrast injection.

The semi-rigid sheath has an internal diameter to allow easy movement over the catheter and an outside diameter sufficient to provide semi-rigid flexibility. The length is 20cm. The distal end is flanged to provide a smooth non-traumatic surface to the tissues.

The syringe is either a 3cc or 6cc size for the 5F or 7F catheter, respectively. The 3cc syringe has a vent at the 1.5cc graduation providing that volume for inflation of the 5F balloon. The recommended volume for the 7F balloon is 4.0cc.

5. Intended use

The Modified Hysterosalpingography Set is to be used for the injection of contrast material in the examination of the uterus and fallopian tubes.

6. Technological characteristics

The materials and construction of the modified hysterosalpingography set with the polyurethane balloon are identical to the approved predicate device with the exception of the inflatable balloon. The characteristics of the proposed polyurethane balloon are at least the equivalent of the Kraton balloons of the predicate device, in terms of safety and effectiveness. (see part B, PERFORMANCE DATA)

B. PERFORMANCE DATA

1. Non-clinical tests

- a. Inflation comparisons showed that the inflated diameter of the polyurethane balloon is not significantly different from the balloons of the predicate device.
- b. Over-inflation of the polyurethane balloons showed that the balloons will withstand a volume of three times the prescribed volume on the label with no ill effects.
- c. The proposed balloon passed a fatigue test of 50 inflation-deflation cycles, representing a five-fold margin of safety over the expected practice in actual use.

2. Biocompatibility

- a. The balloon material is the same as that of the catheter except that the balloon material contains no radiopaque component or pigment, and is completely transparent. The balloon is mounted on the catheter in a manner identical to the predicate device. The polyurethane material used for the catheter tubing has been in use since 1984 in more than 500,000 procedures with no report of any adverse effect on body tissues.

C. CONCLUSION OF SAFETY AND EFFECTIVENESS

The above description, intended use, and technological characteristics of the Modified Hysterosalpingography Set demonstrate that it is substantially equivalent in safety and effectiveness to the predicate device of the same description, K953034.