

SECTION H
510(k) SUMMARY

This section contains a summary of safety and effectiveness for the Mahurkar 8 Fr Catheter as defined in 21 CFR 807.3 and required by 21 CFR 807.92.

(1) *Submitter's name, address, telephone number, contact person, date of preparation:*

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Date summary was prepared: October 27, 1995

(2) *Name of the device:*

Trade Name - Mahurkar Dual Lumen Catheter
Common Names - Hemodialysis Catheter, Apheresis Catheter, Intravascular Catheter
Classification Names -
21 CFR 876.5540 - Non-Implanted Blood Access Devices and Accessories
21 CFR 880.5200 - Intravascular Catheter

(3) *Identification of predicate devices:*

Mahurkar Dual Lumen Catheters (Quinton Instrument Co.; Bothell, WA)
Duo-flow Double Lumen Catheter (MedComp, Inc.; Harleysville, PA)
Safe-Dwel Plus Bi-Lumen Catheter (Becton Dickinson Vascular Access; Sandy, UT)

(4) *Description of the device:*

The Mahurkar 8 Fr Catheter, a radiopaque polyurethane tube with two D-shaped lumina, is coated with silicone fluid. The lumina can be distinguished by the color-coded luer-lock adapters on the clear silicone rubber extensions: the red adapter indicates the proximal lumen, and the blue adapter indicates the distal lumen. During hemodialysis and apheresis, the proximal lumen provides "arterial" outflow from the patient and the distal lumen provides "venous" return.

The Mahurkar 8 Fr Catheter is available in four (4) implantable lengths (9 cm, 12 cm, 15 cm, and 19.5 cm), with straight extensions or curved extensions, and is packaged in catheter kit and catheter tray configurations.

(5) *Intended use of the device:*

The Mahurkar 8 Fr Catheter is intended to be used as a short-term central venous access device for hemodialysis, apheresis, and infusion.

(6) *Comparison to predicate devices:*

The technological characteristics of the Mahurkar 8 Fr Catheter, including catheter type, intended use, insertion method, anatomical placement of catheter tip, number and shape of lumens, catheter tube material, lumen cross sectional area, are similar to those of the predicate devices identified in paragraph (3) of this Summary. The only difference between the Mahurkar 8 Fr Catheter and the predicate devices is the outer diameter (8 Fr), tip design, and one of the available implantable lengths (9 cm).

(7) *Performance data:*

Performance data for the Mahurkar 8 Fr Catheter, including biocompatibility, mechanical characteristics, dynamic flow performance, infusion flow performance, and in vitro hemolysis testing, were compared to that of the predicate devices identified in paragraph (3) of this Summary. These test results demonstrate that the device is substantially equivalent to predicate devices commercially distributed for hemodialysis, apheresis, and infusion.