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# 510(k) SUMMARY

[As required by 21 CFR 807.92]

1. **Submitter and Contact Person**

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2. **Device Name**

Trade Name
Rüsch Simplastic Foley Catheterization Set

Common Name
Urological Catheter

Classification Name
Catheter, Urological 78 KOD
21 CFR 876.5130; Class II medical device

3. **Comparison Devices**

Rüsch Simplastic Foley Catheter - Preamendment
Urotec/Franklin Soft Simplastic Catheters - K851684
Inmed Foley Catheterization Tray - K832363

4. **Description of Device**

The Rüsch Simplastic Foley Catheterization Set contains a pack of lubricating jelly and a Rüsch Simplastic Foley Catheter.

The Rüsch Simplastic Foley Catheters used in the kit will be available:
in 2 way and 3 way formats
in various sizes from 12 - 26 F.G.
in two hardnesses
with various sizes of balloon
with various tip and eye configurations.

Common features of all the catheters are: a clear polyvinyl chloride tube, a radiopaque stripe of $BaSO_4$ loaded PVC is fully encapsulated in the tube wall, a latex balloon attached by adhesive bonding, a funnel connected to the main lumen and a luer activated valve for filling and emptying the balloon.

5. **Intended Use**

The Rüsch Simplastic Foley Catheterization Set contains:

one Rüsch Simplastic Foley Catheter
one pack of lubricating jelly.

The Rüsch Simplastic Foley Catheter is intended to be used to pass fluids to and from the urinary tract. A pack of lubricating jelly is intended to assist insertion of the catheter through the urethra.

6. **Summary of Technological Characteristics**

The Rüsch Simplastic Foley Catheterization Set is manufactured from the same materials and by the same processes (including sterilization) as the Rüsch Simplastic Foley Catheter (preamendment) and Urotec/Franklin Soft Simplastic Catheters (K851684), and contains the same "gel" pack as the Inmed Foley Catheterization Tray (K832363).

Sterile catheters have been biocompatibility tested in accordance with ISO 10993 and the FDA "Blue Book Memo" #G95/1.

7. **Summary of Performance Data**

Laboratory bench testing has been completed to section #XI of the FDA "Draft Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters":

drainage lumen flow rate
balloon resistance to rupture
pullout resistance of inflated balloon
maintenance of balloon inflation over extended time
manufacturing tolerances for tip, balloon and shaft
deflation after period of inflation
biocompatibility testing for patient contacting materials