

K962472

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RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

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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 Urodynamic Rectal Balloon 2-way Catheter

Common Name

Urodynamic Rectal 2-way Catheter

Classification Name

Accessory to Urodynamics Measurement System
78 FAP; 21 CFR 876.1620; Class II medical device

3. **Comparison Devices**

Rüsch Urodynamic Rectal Balloon Catheter - K952573
Porges Urodynamic Rectal Balloon Catheter - Preamendment
Cook Urological Urodynamic Rectal Balloon Catheter - K912451

4. **Description of Device**

The Rüsch Urodynamic Rectal Balloon 2-way Catheter consists of a double lumen polyvinyl chloride tube upon which is affixed a latex balloon, with a radiopaque stripe.

To use, the balloon is inflated with sterile water using a luer taper syringe. The catheter is then connected to a transducer, and can be used in conjunction with equipment for calculating the detrusor pressure (pressure necessary to open the urinary sphincter).

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5. **Intended Use**

The Rüsç Urodynamic Rectal Balloon 2-way Catheter is intended to provide a fluid conduit for urodynamic studies, where the detrusor pressure is to be calculated from rectal pressure.

6. **Summary of Technological Characteristics**

The Rüsç Urodynamic Rectal Balloon 2-way Catheter is manufactured of the same materials and by the same processes (including sterilization) as the Rüsç Urodynamic Rectal Balloon Catheter - K952573.

The Rüsç Urodynamic Rectal Balloon 2-way Catheter has a double lumen shaft design similar to the Porges Urodynamic Rectal Balloon Catheter (Preamendment) and the Cook Urological Urodynamic Rectal Balloon Catheter (K912451).

7. **Summary of Performance Data**

Biocompatibility testing has been completed based on the ISO 10993 matrix modified by FDA Blue Book Memo #G95/1.

Laboratory bench testing has been completed to section #6 of the FDA "510(k) Checklist for Urodynamic Catheters":

Tensile Testing

Balloon Burst Testing

The device's performance in these tests is comparable with that of the Rüsç Urodynamic Rectal Balloon Catheter (K952573).