

APR - 2 1997

K970308

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SUMMARY OF SAFETY AND EFFECTIVENESS
MENTOR UROLOGY TRIPLE RIB OCCLUSION WRAP FOR
MALE INCONTINENCE
(510K SUMMARY)

1. Submitter's Data

Mentor Urology, Inc.
1615 West River Road North
Minneapolis, MN 55411

Date Prepared: 23 January 1997

2. Device Name, Classification

Name: Mentor Urology Triple Rib Occlusion Wrap for Male Incontinence

Trade Name: To be determined

FDA Classification: Class I per 21CFR876.5250, Urological Clamp for Males,
Code 78FHA.

3. Identification of Substantially Equivalent Device

Bard Cunningham Incontinence Clamp, #K884426

4. Device Description

The Mentor Urology Triple Rib Occlusion Wrap for Male Incontinence is a two piece compression device for males with urinary incontinence. The device consists of a silicone gel filled penile compression wrap for occlusion of the urethra and a silicone ring. It is intended for users who would prefer a reusable soft sided device instead of a rigid clamping device. The device is intended for users with moderate to heavy urinary incontinence to provide a temporary means of urinary continence.

5. Indications for Use

The Mentor Urology Triple Rib Occlusion Wrap for Male Incontinence is indicated for any male, who has urinary incontinence, either on a temporary or long term basis. It is also indicated for those patients who have an adverse reaction to natural latex rubber.

6. Contraindications for Use

Clinical contraindications for use of the Mentor Urology Triple Rib Occlusion Wrap for Male Incontinence include:

Use on patients with broken or poor skin quality.

Use on patients with adverse reactions to any component of the system.

7. Warnings, Precautions

Patient skin must be clean and dry before use.

The correct size must be used. Physician advise may be helpful.

8. Biological Safety Testing

Mentor Urology has performed biological safety testing on all components used in this device. These tests meet or exceed Tripartite and ISO 10993 standards. All tests were satisfactory.

9. Physical Testing, Design Verification

Mentor Urology has performed various physical tests on this device and its components to show that the device and its design are adequate for the use intended.