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510(k) - INTROL* Bladder Neck Support Prosthesis with Removal Tool

510(k) SUMMARY

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INTROL* Bladder Neck Support Prosthesis with Removal Tool

1. **DATE PREPARED**

December 16, 1996

2. **SUBMITTER**

Johnson & Johnson Medical, Inc.
2500 Arbrog Boulevard, P.O. Box 90130
Arlington, Texas 76004-3130

3. **CONTACT**

Ralph H. Larsen., (817)784-4993
Sr. Project Manager, Regulatory Affairs

4. **NAME OF THE MEDICAL DEVICE**

Classification name: Pessary, vaginal
Common/usual name: Vaginal Pessary
Proprietary name: INTROL* Bladder Neck Support Prosthesis with Removal Tool

5. **DEVICE CLASSIFICATION**

The INTROL* Bladder Neck Support Prosthesis with Removal Tool has been classified by the FDA under the heading of Vaginal Pessary 85HHW as a Class II device.

6. **STATEMENT OF SUBSTANTIAL EQUIVALENCE**

INTROL* Bladder Neck Support Prosthesis with Removal Tool is substantially equivalent and identical in function to INTROL Bladder Neck Support Prosthesis marketed by Johnson & Johnson Medical, Inc.

7. **INDICATIONS FOR USE**

The INTROL* Bladder Neck Support Prosthesis with Removal Tool is indicated for the temporary management of genuine stress urinary incontinence.

8. **PHYSICAL DESCRIPTION**

The INTROL* Bladder Neck Support Prosthesis with Removal Tool is identical in all aspects to INTROL* Bladder Neck Support Prosthesis except for the addition of the Removal Tool. The Removal Tool is a rod shaped device, about 7 inches in length with a hook at one end and a handle at the opposite end. The handle is marked with a flat surface about 0.25 inch in width and 4 slightly elevated rings, each about 1 inch apart. The flat handle surface is on the same side of the tool as the open portion of the hook. This configuration indicates the direction of the functioning portion of the hook. The rings are present to enhance the grip of the tool and to enable the user to gauge the depth of the tool once it enters the vagina. The hook is designed to easily engage the front portion of the INTROL* Prosthesis's ring. The Removal Tool surface is smooth. The Removal Tool is composed of high density polypropylene and titanium dioxide pigment.

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INTROL* Bladder Neck Support Prosthesis is made from a medical grade silicone elastomer. The prosthesis is circular and symmetrically shaped with a central aperture and two ridges.

7. **BIOCOMPATIBILITY**

Safety tests demonstrate that INTROL* Bladder Neck Support Prosthesis with Removal Tool is non-sensitizing, and non-irritating and suitable for its intended use.

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