

510(k) 72

**SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS INFORMATION**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K954272

K954272

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**Identification:**

Classification Name: Nonimplanted Electrical Continence Device  
 Common/Usual Name: Rectal Stimulation Electrode  
 Trade/Proprietary Name: Innova Rectal Stimulation Electrode

**Equivalent Devices:**

Innova Vaginal Stimulation Electrode (K910081, K940091)  
 InCare Rectal Electrode (K891773)

**Product Description:**

The Innova Rectal Stimulation Electrode assembly is a light-weight cylinder consisting of two conductive rings that are paired and isolated, physically and electrically. The cylinder is shaped with a waist and a handle for comfort, positioning and ease in removing. It is watertight to allow for washing with soap and water between uses. The electrode is designed for repeated intermittent use in the home or clinic for up to one year by a single user. It does not require sterilization, but does require washing with soap and water and drying between uses.

**Intended Use:**

The Innova Rectal Stimulation Electrode is designed for use with the Innova PFS System which has market clearance for the treatment of urinary incontinence.

**Product Verification and Validation:**

The following parameters were tested: leadwire placement and integrity, impedance; tensile strength; connection strength; flexion; label durability; surface integrity, material integrity (mechanical shock); material stability; dimensions; and material biocompatibility. The results of the functional testing were analyzed against product specifications and demonstrate that the product meets requirements and is acceptable for its intended use.

**Clinical Testing:**

An acute clinical test was performed to verify that the Innova Rectal Stimulation Electrode could produce a pelvic floor contraction equal to or greater than the InCare Rectal Electrode. The results showed that:

1. All subjects had pelvic muscle contractions using both electrodes that were of sufficient amplitude to produce an observable and measurable response at maximum comfortable intensity.
2. The maximum comfortable current intensity achieved with the Innova rectal electrode was significantly higher than with the InCare rectal electrode ( $p < 0.05$ ).
3. The contraction induced pressures achieved with the Innova rectal electrode were significantly higher than the pressures achieved with the InCare rectal electrode ( $p < 0.01$ ).
4. The maximum current density attained with the Innova rectal electrode was significantly lower than with the InCare rectal electrode ( $p < 0.01$ ).

No adverse effects were noted by the investigator in any of the subjects tested.

**Conclusion from Non-Clinical and Clinical Testing**

The data obtained from the non-clinical and clinical tests demonstrate that this electrode is as safe, as effective and performs as well or better than the InCare Rectal Electrode.

**Comparison of Product Specifications**

See the following chart for details on the similarities and differences of the predicate devices and the Innova Rectal Stimulation Electrode.

**COMPARISON OF INNOVA RECTAL ELECTRODE SPECIFICATIONS TO PREDICATE DEVICES**

<b>Electrode Characteristics</b>	<b>InCare Rectal Electrode</b>	<b>Innova Rectal Electrode</b>	<b>Innova Vaginal Electrode</b>
<b>Premarket Notification</b>	Stimulation - K891773 EMG Sensing - K891774	<b>Current Submission</b>	Stimulation - K910081 EMG Sensing - K940091
<b>Number Of Electrodes</b>	2 - Stimulation	2 - Stimulation	3 - Sensing 4 - Stimulation
<b>Biocompatibility</b>	Unknown	<b>Meets ISO 10993 and USP class VI</b>	Meets the Tripartite Guidance and USP class VI
<b>Usage Conditions</b>	<i>Reusable single patient use</i>	<b>Reusable single patient use</b>	<i>Reusable single patient use</i>
<b>Electrode Orientation</b>	<i>Circular</i>	<b>Circular</b>	<i>Circular</i>
<b>Body Material</b>	plastic	<b>Medical-Grade Santoprene</b>	<i>Medical-Grade silicone rubber</i>
<b>Insertable Length</b>	<i>2.3 in. nominal</i>	<b>2.4 in. nominal</b>	3 in. nominal
<b>Diameter (Max.)</b>	0.6 in. nominal	<b>0.8 in. nominal</b>	1 in. nominal
<b>Electrode Material</b>	Metal	<b>Carbon loaded Santoprene</b>	Carbon loaded silicone rubber
<b>Electrode Spacing</b>	0.32 in. nominal	<b>0.43 in. nominal</b>	1.7 in. nominal
<b>Active Surface Area (nominal)</b>	0.3 in <sup>2</sup> /band	<b>0.9 in<sup>2</sup>/band</b>	1.9 in. <sup>2</sup> /band
<b>Electrode Placement</b>	<i>Rectum</i>	<b>Rectum</b>	Vagina
<b>Device Connection</b>	Attached cord with 3.5mm phone plug.	<b>Attached cord with custom 2.5mm 2 pin plug*</b>	<i>Attached cord with custom 2.5mm 2 pin plug*</i>
<b>Max. Power Density</b>	81 mW/cm <sup>2</sup>	<b>51 mW/cm<sup>2</sup></b>	24.45 mW/cm <sup>2</sup>
<b>Max. Current Density</b>	6.5 mA/cm <sup>2</sup>	<b>3.0 mA/cm<sup>2</sup></b>	1.41 mA/cm <sup>2</sup>
<b>Contact Duration</b>	Unknown	<b>Intermittent mucosal contact &lt; 30 days but &gt; 24 hours</b>	<i>Intermittent mucosal contact &lt; 30 days but &gt; 24 hours</i>
<b>Indications For Use</b>	<i>Electrical stimulation of the pelvic floor muscles for the treatment of incontinence; EMG sensing of the pelvic floor muscles.</i>	<b>Electrical stimulation of the pelvic floor muscles for the treatment of incontinence</b>	<i>Electrical stimulation of the pelvic floor muscles for the treatment of incontinence; EMG sensing of the pelvic floor muscles.</i>

Note: The italics indicate parameters which are the same or equivalent.

\*Meets the proposed performance standard, described in FR Volume 60, No. 119, in that the pins are set too closely together to allow insertion into a wall socket or power cord such that conductive contact would occur without damaging the connector.