6 June 1995 **DRAFT**

510(k) Checklist for Non-implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence

The purpose of this 510(k) checklist is to identify the type of information to be provided in a premarket notification (510(k)) to support a determination of substantial equivalence for nonimplanted electrical continence devices. While most of the criteria listed in this 510(k) checklist have been utilized by the Urology and Lithotripsy Devices Branch (ULDB) in the review of these devices for some time, the performance data section contains new and simplified requirements. Specifically, ULDB now believes that data from an acute, short term study investigating the device's physiologic effect on the patient (e.g., muscle contraction), rather than data from a larger scale incontinence study, may be adequate to assess equivalence. Additional details regarding the design of this study are provided in section 5 of this checklist. Any comments or questions regarding this new policy or any aspect of the checklist are welcome and may be communicated to:

Urology and Lithotripsy Devices Branch
Division of Reproductive, Abdominal, Ear,
Nose and Throat, and Radiological Devices
Office Of Device Evaluation
Center for Devices and Radiological Health
(301) 594-2194.

General guidance for the preparation of a 510(k) submission is provided in the DRAERD "Draft Guidance for the Content of Premarket Notifications." Additionally, guidance on the preparation of a 510(k) is available in our "Center for Devices and Radiological Health Premarket Submissions Cover Sheet," which we are requesting that manufacturers use in the preparation of any type of premarket submission, as part of a pilot program. Additional guidance on device modifications is provided in the draft document "Deciding When to Submit a 510(k) for Change to an Existing Device." These documents are available from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597.

Adequate ?

1. Administrative information:

A. Classification name - Nonimplanted Electrical Continence Device _____

B. Device/Trade name _____

C. Sponsor/manufacturer name and address _____

D. Procode/Classification - 78 KPI, Class II, (§ 876.5320) _____

E. Establishment registration number _____

F. Special Controls - None established _____

2. Reason for the 510(k) submission (new device or a modification to an existing device) _____

3. Intended use of the device: _____

A non-implanted electrical stimulator for urinary incontinence is intended to retrain the urinary continence mechanisms by way of electrical stimulation applied to the pelvic floor musculature and surrounding structures. Typically, these devices are indicated for use in females for treatment of stress incontinence, urge incontinence, or mixed incontinence (a combination of stress and urge incontinence).

4. Device description

For the purposes of this guidance, the term "applicator" refers to the vaginal pessary-like device and/or rectal probe. The term "electrode" refers to the metal, carbon loaded silicone, or other material component on the applicator that conducts the electrical energy to the patient.

A. List of the device's components/parts

i. battery and/or AC powered* external stimulator _____
ii. vaginal applicator(s) _____
iii. rectal applicator(s) _____
iv. applicator cleaner (including chemical makeup if not the same as the predicate cleaner) _____

* although AC powered stimulators are excluded under 876.5320, legally marketed predicate devices do exist which are AC powered.

B. Electrical Characterization

i. external stimulator

a. minimum and maximum current output or voltage output (whichever remains constant over varying loads). _____

minimum:

maximum:

b. graphical representation of waveforms at full power with loads simulating clinical use (e.g., 100, 500, 1kΩ; although other loads may be proposed with appropriate justification) - axes should be labeled with units of measure _____

c. the maximum charge per pulse (this value should not exceed 75 μC/pulse[1]). For biphasic signals, assume the worst case by adding the charge associated with both pulses _____

maximum charge/pulse:

d. discussion of safety features provided to limit maximum current or voltage _____

[1] American National Standard for Transcutaneous Electrical Nerve Stimulators. AAMI/ANSI, NS4-1985

e. explanation of whether the electrodes are electrically isolated from the power supply _____

f. stimulation frequency _____

frequency #1:

frequency #2:

frequency #3:

g. peak pulse intensity: _____

h. pulse width: _____

i. ramp up/down times _____

ramp up:

ramp down:

j. duty cycle: _____

k. identification of programmable features (if applicable) _____

features programmable by physician _____
features programmable by patient _____

l. a discussion of any biofeedback components (if applicable) _____

ii. applicators

a. maximum current density for each size electrode; provide calculations _____

maximum $I_{density}$:

b. maximum power density for each size electrode; provide calculations (Note, for TENS electrodes a power density of 0.25 w/cm^2 can produce burns)[2] _____

iii. electromagnetic interference (EMI) _____

The device should be tested to electromagnetic compatibility (EMC) standards. Immunity testing should be performed to demonstrate that the device functions satisfactorily in the intended use environment. Emissions testing should be performed to demonstrate that the device does not emit electromagnetic energy that interferes with other equipment. Note that FDA will consider an appropriate justification for why such testing is not necessary. EMC should be addressed in the labeling.

C. Applicator Physical Description

i. dimensions of each applicator, including dimensions of each electrode _____

ii. surface area of each electrode of each applicator _____

iii. material identification of applicator and _____

electrodes

D. Diagrams, engineering drawings, and/or photographs of the device _____

[2] Office of Device Evaluation, Food and Drug Administration: Guide for TENS 510(k) Content, R Munzner, W Burdick, July 1992

E. Explanation of whether or not the device is software controlled (if so, this aspect of the device should be discussed according to the draft FDA guidance document "Reviewer Guidance for Computer Controlled Medical Devices undergoing 510(k) Review"). The device typically represents a moderate level of concern as defined in the guidance document. _____

5. Performance Data (for devices with differences in technological characteristics) _____

In regulating nonimplanted electrical continence stimulators, FDA must take into account the current body of knowledge regarding these products. While continence stimulators have a relatively long history of use, little data are available from controlled clinical studies to determine how design and/or treatment regimen differences affect clinical performance. Additionally, relatively little data are available investigating the mechanism of action associated with these devices (notably for the indication of urge incontinence). Relating these circumstances to the 510(k) decision making process[3], performance data are often needed because the descriptive characteristics alone (e.g., stimulation frequency, treatment regimen, applicator design, etc.) are insufficiently precise to ensure equivalence with respect to performance unless the designs of the new and predicate stimulators and applicators are virtually identical.

This policy is consistent with the Agency for Health Care Policy and Research's Clinical Practice Guideline for urinary incontinence which states, "Research is needed to determine the efficacy of electrical stimulation either when used alone or in combination with other management strategies to treat [urinary incontinence] ... Ideal parameters for electrotherapies have not been established by controlled clinical trials, and research needs to be conducted before this technique becomes a standard treatment for [urinary incontinence]."[4]

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[3] 510(k) Decision Making Process (Detailed), Blue Book Memorandum #86-3, 1986

[4] Urinary Incontinence Guideline Panel. *Urinary Incontinence in Adults: Clinical Practice Guideline.* AHCPR Pub. No. 92-0038. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. March 1992.

Accordingly, FDA believes that performance data from a short term, acute clinical study are needed to assess equivalence, if differences in technological characteristics (e.g., stimulation frequencies, treatment regimens, electrode surface areas, etc.) exist between the new device and predicate device. This short-term clinical study should be designed to demonstrate that the physiologic response (e.g., muscle contraction) produced by the new device is equivalent to the physiologic response produced by the predicate device. Accordingly, both the new device and the predicate device should be tested. The information to be collected could include electromyographic (EMG) evoked potential data (in response to electrical stimulation) and/or pressure biofeedback data from a pressure sensor placed intravaginally or intrarectally (to record the pressure generated by the contraction of the pelvic floor musculature as produced by the electrical stimulation). In order to ensure that the data produced will be adequate for a premarket notification, we encourage manufacturers to submit their proposed clinical protocols to FDA for comment.

This study will allow comparisons between the new and predicate devices regarding the acute physiologic response to electrical stimulation, but will not allow comparisons regarding the long term therapeutic outcome since the relationship between a specific physiologic response (e.g., a muscle contraction of a specific magnitude) and the long term therapeutic outcome is not known. FDA therefore encourages manufacturers to conduct additional clinical trials to investigate the long term safety and effectiveness issues which remain unanswered regarding these devices. When such data are available, a new 510(k) can be submitted with revised labeling which incorporates the results of this clinical trial (e.g., determination of optimal treatment regimens for various etiologies of urinary incontinence).

Please note that a clinical study investigating a conventional non-implanted electrical stimulator for urinary incontinence can be performed without the submission of an investigational device exemptions (IDE) application to FDA, provided the sponsor of the investigation and reviewing institutional review board(s) make the determination that the study does not present a significant risk. However, electrical stimulators with design features that are significantly different than conventional stimulators, e.g., stimulators with high power output, may require the

submission of an IDE. For additional information regarding significant versus nonsignificant risk device studies, please refer to the memorandum, Guidance on Significant and Nonsignificant Risk Device Studies, (available from DSMA).

5. General electrical safety

Standards with which the device complies (e.g., UL 544 or IEC 601) _____

6. Proposed labeling, instructions for use, advertisements (in accordance with the Device Labeling Guidance Document available through DSMA)

a. Intended use _____

b. Complete instructions for use (for both the physician and patient), which should include: _____

i. the treatment regimen _____

ii. instructions on how to select the proper pulse intensity level. _____

c. Maintenance/cleaning instructions _____

d. Prescription device statement _____

e. Patient outcome information (e.g., success rate, time from initiation of treatment until improvement is noted, optimal treatment regimens for various incontinence etiologies, adverse events, etc.) should be provided if data from long term clinical trials are available. _____

7. Biocompatibility

a. List of the materials that contact the patient _____

b. For all of the materials that contact the patient (including color additives), provide either:

i. Certification that the same formulations of these materials are used in another, similar legally marketed device (provide the device name, manufacturer, and (if possible) 510(k) number); OR _____

ii. The results of the following biocompatibility tests: (1) mucosal irritation, (2) cytotoxicity, (3) acute systemic toxicity, (4) sensitization, (5) 7 day implantation with histopathology, and (6) subchronic toxicity _____

FDA will consider an appropriate justification for the deletion of some of the above tests.

8. Sterility information as per Blue Book memorandum #K90-1 (if applicable) _____

9. Comparison to a legally marketed predicate device

a. Name/manufacturer of predicate device _____

b. Labeling of predicate device (including treatment regimen) _____

c. Intended use of predicate device _____

d. Description of predicate device as stated in section 4 of this checklist which includes:

i. list of components _____
ii. electrical characteristics _____
iii. physical characteristics _____

e. Diagrams/photographs of the predicate device _____

f. 510(k) number of the predicate device, if known (or statement that the predicate is a preamendments device) _____

g. A detailed comparison of the similarities and differences between the 510(k) device and the predicate device (in tabular format) _____

10. 510(k) Summary/Statement _____
see 21 CFR 807.92 and 807.93

11. Truthful and Accurate Statement _____
signed and in accordance with 21 CFR 807.87(j)