EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO) FOR AHIP INTERNAL TRIGGER POINT WAND

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> Internal therapeutic massager. A hand-held internal therapeutic massager device is a prescription device intended for medical purposes to manually provide direct pressure applied to localized areas of pain or tenderness in the myofascial tissue associated with chronic pelvic pain syndromes. The device is inserted rectally or vaginally and provides quantitative feedback to the user of the applied force to the target tissue.

NEW REGULATION NUMBER: 21 CFR 890.5670

CLASSIFICATION: II (exempt from premarket notification subject to 21 CFR 890.9)

PRODUCT CODE: OSD

BACKGROUND

DEVICE NAME: AHIP Internal Trigger Point Wand

510(K): K100934

DATE OF 510(K) NSE DECISION: July 27, 2010

DATE OF DE NOVO PETITION: August 17, 2010

PETITIONER CONTACT:
National Center for Pelvic Pain Research Devices, Inc.
12470 Fiori Lane
Sebastopol, California 95472

PETITIONER'S RECOMMENDED CLASSIFICATION: II

INDICATIONS FOR USE

The AHIP Internal Trigger Point Wand is a self-massager used to massage irritable, sore trigger points in the pelvic floor musculature to reduce internal pelvic floor trigger point sensitivity. It helps to relieve painful trigger points through this direct, manual therapeutic massage technique. Painful intrapelvic trigger points are associated with chronic pelvic pain syndromes.

LIMITATIONS

The sale, distribution, and use of the device are restricted to prescription-use only.

Limitations on device use are also achieved through the following statements included in the Instructions for Use Manual:

Safety and effectiveness of use of this device has not been demonstrated in persons less than 18 years of age, or over 70 years of age.

This device should not be used by persons who lack the mental capacity to comprehend and follow the instructions for safe use of this device.

The prescriber is instructed to evaluate and confirm that the patient's pain is myofascial pelvic pain syndrome in origin and other causes have been ruled out before the use of this device.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

CONDITIONS OF EXEMPTION

Internal therapeutic massagers, when it is a prescription use device, are appropriate for exemption from premarket notification, subject to the limitations of exemptions identified in 21 CFR 890.9, because the applicable special controls and general controls provide reasonable assurance of safety and effectiveness if device manufacturers follow the special controls requirements. Examples exceeding the limitations of exemption include indications for over-the-counter use, lack of a quantitative feedback mechanism, and lack of a disposable covering.

Exemption from the requirement of premarket notification for internal therapeutic massagers does not mean that these devices would be exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. FDA's proposal to exempt these devices from the requirement of premarket notification is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements (21 CFR part 820) and the identified special controls, provide.

DEVICE DESCRIPTION

The AHIP Internal Trigger Point Wand is a single-patient-use internal therapeutic massager as depicted in Figure 1. The wand (ULTEM®) consists of a ball pressure applicator (Santoprene™) on a rod with a distal hook-shaped curve. A strain gauge is attached to the straight portion of the wand, which is connected to a battery-operated readout device that measures the amount of pressure being exerted at the tip of the wand. The wand also has an adjustable "stop" (to be set by the therapist) to limit the depth of insertion. The wand is to be covered with a disposable covering and lubricant (e.g., FDA-cleared KY-Jelly or other water-based lubricants without sensates) prior to use.

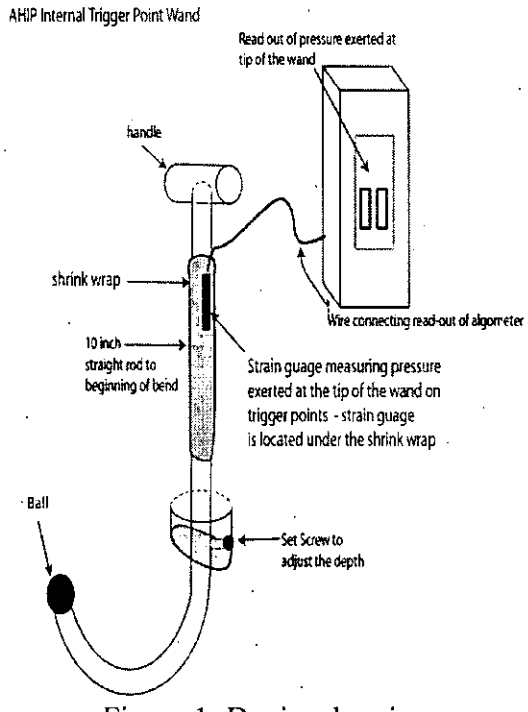

Figure 1: Device drawing

Please refer to the Instructions for Use for additional details.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The device is to be covered with a disposable covering during use. The biocompatibility profile for the patient-contacting portion of the device (ball and wand) was considered in the event of breakage of the disposable covering. The biological evaluation included biocompatibility testing on the raw materials, which are medical-grade, as outlined in ISO 10993-1:2003, and provided a justification that the manufacturing process will not impact the biocompatibility. An appropriate test panel was conducted and the results met the testing criteria. In conclusion, based on biocompatibility assessment of the information provided, there is reasonable assurance of safety with respect to the intended use.

STERILITY/SHELF LIFE/REUSE

The AHIP Internal Trigger Point Wand is provided non-sterile and for single-person use. The device is to be covered by a disposable covering and is not being used in a sterile environment.

The device does not have a stated shelf life. Based on the nature of the device components (i.e., rod wand, display gauge), the absence of a shelf life is acceptable.

The covering is a single-use disposable component. Because this component is not labeled for reuse, validation of the cleaning methods and instructions was not necessary. To mitigate the potential for cross-contamination, a disposable covering is used and replaced after each use.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The device was tested to address compliance with the requirements of IEC 60601-1 (3rd edition) "*Medical Electrical Equipment – Part 1: General Requirements for Safety*" and IEC 60601-1-2 (3rd edition) "*Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard 2; Electromagnetic Compatibility – Requirements and Tests*" standards. The test reports, results and labeling were determined to be sufficient to provide reasonable assurance of the device's electromagnetic compatibility and electrical safety.

SOFTWARE

The software for the device presents a minor level of concern based on answers to the questions listed in FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005). Considering the nature of the device and the limitations on its use (i.e., a gauge solely to be used as a reference tool), there is no potential for a failure or design flaw in the software to result in injury, erroneous diagnosis, or a delay in delivery of appropriate medical care.

The software provides data acquisition from the strain gauge.

The petition includes a device hazard analysis, which contains a tabular description of identified hardware and software hazards, including severity assessment and mitigation measures.

Verification and validation testing documentation includes the following expected elements for a minor level of concern: functional test plan, pass / fail criteria, and summary of results. The documentation provides sufficient evidence that the specified requirements have been fulfilled.

All expected elements of software documentation (per FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff) are included in the petition and in sufficient detail to provide reasonable assurance that the software performs as intended and all software-related risks have been adequately mitigated.

PERFORMANCE TESTING – BENCH

Performance of the device included mechanical testing of the wand (i.e., tensile test) and validation testing of the gauge (i.e., gauge response time and force measurement range).

In the tensile test, force to the wand was applied to the point of failure. The results of the tensile test demonstrated that the strength of the ball attachment well exceeded the force expected to be applied during treatment. The results of the validation test verified the gauge response time and force measurement range up to the force expected to be applied during treatment. The display feedback mechanism was also validated to ensure repeatable readout of applied force.

SUMMARY OF CLINICAL INFORMATION

Clinical data included a 393-patient prospective clinical trial compared with a historical control. The study population included 314 male and 79 female patients between 18-80 years old, who were diagnosed with muscle related pelvic pain, dysfunction and symptoms. However, note the safety and effectiveness of this device has not been demonstrated in persons over 70 years of age because there were few subjects presented over the age of 70.

Following a training period with a physician or physical therapist, subjects demonstrated proper use of the device, including the use of the device with a disposable covering and lubricant, and were instructed to use the device at home up to six months. The following were collected at one-month and six-month follow-up intervals: a) The amount of force applied internally, the duration of use, the level of sensitivity on a scale from one to ten (one being "least sensitive" to ten being "most sensitive") and b) the level of satisfaction and the level of treatment effectiveness with the use of the device on a scale from one to three (one being "very satisfied" to three being "not satisfied"). Results for a final sample size of 219 were reported, which included 143 withdrawals and 31 who had not completed the study by the data cutoff period. Considering the chronic pain population and the time commitment for participation, 23% of withdrawals were patients lost to follow-up and the remainder were related to a variety of reasons including pain resolution, preference for other treatment methods, schedule too busy, unrelated medical conditions, etc. After a six-month follow-up, 87.7% of the 219 subjects reported a reduction in sensitivity, 94.1% reported being very or moderately satisfied, and 94.5% reported very or moderately effective treatment with the use of the device. Therefore, patients self-reported high satisfaction and effectiveness of the treatment with this device. Overall, the clinical data demonstrated a measurable benefit for both males and females.

In addition, no serious adverse events were reported in the study. However, there were a total of 23 non-serious adverse events reported, which includes 15 reports of soreness and 8 reports of minor transient bleeding. These adverse events resolved without medical intervention. In addition, there were 30 reports of device malfunctions (e.g., battery drainage and feedback mechanism miscalibration mostly with the earliest iteration of the circuit board) that was resolved after repair or with a new device. Overall, the clinical data demonstrated a low risk profile for this device.

Clinical data also included a retrospective study comparing a subcohort of the above study with a historical control consisting of patients who completed a similar training and treatment program of pelvic floor trigger point release therapy without use of the device. Outcomes were evaluated for the change in overall symptoms from baseline. The data from the NIH-CPSI score for the Immersion patients (historical control, n=82) was compared to a Wand CPSI (W-CPSI) score for

the device cohort (n=75). The W-CPSI is not an actual tool, but a summary score based on similar questions that were recorded in the prospective study, namely the numerical rating scale (1 to 10) based responses to Total Symptoms and Emotional Distress. The sum of the two questions represents the W-CPSI score and it can range from 2-20. The results showed that 76% of subjects in the device cohort self-reported a ≥20% difference in Wand CPSI from baseline to 6 months follow-up, compared to 57.32% of subjects in the control cohort who self-reported a ≥20% difference in NIH-CPSI score from baseline to follow-up times between 3-12 months. Although the assessment tools utilized for both groups are not identical, the data further demonstrated a measurable benefit with the use of the device compared to alternative treatment.

Therefore, the study provided adequate clinical data to support the safety and effectiveness of this device in both males and females.

LABELING

Labeling has been provided which includes instructions for use and a prescription use statement as required by 21 CFR 801.109. The labeling has been written to help ensure that sufficient instructions are provided to limit the likelihood of (1) user error, (2) tissue irritation/allergy, (3) tissue bruising, abrasion or tearing, (4) microbial contamination from reusable components, (5) vaginal/rectal cross-contamination, (6) overstretching/weakness of the anal sphincter and vagina, (7) electromagnetic incompatibility, and (8) electrical hazards .

The risk of improper use is mitigated through labeling by including instructions stating that:

- The prescriber evaluate and confirm that the patient's pain is myofascial pelvic pain syndrome in origin and other causes have been ruled out.
- The prescriber educate the user on the proper use of the device and guide the patient in locating myofascial trigger points.
- The device should not be used by persons who lack the mental capacity to comprehend and follow the instructions for safe use of the device.
- Safety and efficacy of use of this device has not been demonstrated in persons less than 18 years of age, or over 70 years of age.

The risk of tissue irritation/allergy is mitigated through labeling by including instructions stating that patients with latex allergies should not use latex disposable coverings and lubricants with spermicides or sensates should not be used.

The risk of tissue bruising, abrasion or tearing is mitigated through labeling by including instruction statements explaining the meaning of the gauge display, checking the gauge display for recalibration, and using the gauge display as a reference tool and not as the primary factor in determining how much force to apply.

The risk of microbial contamination from reusable components is mitigated through labeling by including instructions stating that the device is limited to single patient use; the reusable components are to be covered with a new disposable cover before each use.

The risk of vaginal/rectal cross-contamination is mitigated through labeling by including instructions stating that separate disposable covers and lubricants are to be used when inserting the device either vaginally or rectally.

The risk of overstretching/weakness of the anal sphincter and vagina is mitigated through labeling by including instructions to generously lubricate the insertion treatment area (i.e. anal sphincter or vagina) and to slowly insert or remove the device.

The risk of electromagnetic incompatibility and electrical hazards are mitigated through labeling in compliance with the requirements of IEC 60601-1:1998 "*Medical Electrical Equipment – Part 1: General Requirements for Safety*" and IEC 60601-1-2:2007 "*Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard 2; Electromagnetic Compatibility – Requirements and Tests*" standards.

RISKS TO HEALTH

The table below identifies the risks to health that are associated with use of the internal therapeutic massager and the measures to mitigate these risks.

Identified Risk	**Mitigation Method**
Tissue irritation/allergy	Biocompatibility testing Labeling
Tissue bruising, abrasion or tearing	Performance testing Labeling
Microbial contamination from reusable components	Labeling
Vaginal/rectal cross-contamination	Labeling
Overstretching/weakness of the anal sphincter and vagina	Performance testing Labeling
Mechanical failure during use	Performance testing
User error	Labeling
Electrical hazards	Electrical safety testing Labeling
Electromagnetic incompatibility	Electromagnetic compatibility testing Labeling
Software failure	Software testing

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the AHIP Internal Trigger Point Wand is subject to the following special controls:

1. The labeling must include adequate directions for use, including prescribing information, to ensure safe and effective use by the patient;
2. Appropriate analysis/testing must validate electromagnetic compatibility (EMC), electrical safety and mechanical safety;

3. Non-clinical performance testing must demonstrate a reasonable assurance of safety and effectiveness, including mechanical durability and accurate feedback mechanism;
4. Appropriate software verification, validation, and hazard analysis must be performed; and
5. All elements of the device that may contact the patient must be demonstrated to be biocompatible.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

BENEFIT/RISK DETERMINATION

The risks of the device are based on data collected in a clinical study described above. No serious adverse events were reported in the study. Approximately 5.9% reported non-serious, temporary adverse events, which included 15 reports of soreness and 8 reports of minor transient bleeding. These adverse events resolved without medical intervention. In addition, there were 30 reports of device malfunctions (e.g., battery drainage and feedback mechanism miscalibration mostly with the earliest iteration of the circuit board) that was resolved after repair or with a new device. Overall, the clinical data demonstrated a low risk profile for this device.

The probable benefits of the device are also based on data collected in a clinical study as described above. After a six-month follow-up, the results of the study showed 87.7% of the 219 subjects self-reporting a reduction in sensitivity, 94.1% reporting very or moderately satisfied, and 94.5% reporting very or moderately effective treatment with the use of the device. Overall, the clinical data demonstrated a measurable benefit for both males and females.

Additional factors were considered in determining probable risks and benefits for the AHIP Internal Trigger Point Wand. Currently available therapies for this condition poorly meet the medical need that this device addresses. Based on clinical experience, the device is desirable to the patient population because they are willing to tolerate the low risk of this treatment to achieve the benefit.

In conclusion, given the available information above, the data supports that for massaging irritable, sore trigger points in the pelvic floor musculature to reduce internal pelvic floor trigger point sensitivity, the probable benefits outweigh the probable risks. Overall this device, based on the clinical evidence, has a high benefit and low risk. However, this evidence also suggests that the individual patient's benefit from the device will be variable. The device provides substantial benefits and the risks can be mitigated by the use of general and special controls.

CONCLUSION

The de novo petition for the AHIP Internal Trigger Point Wand is granted and the device is classified under the following:

Product Code: OSD
Device Type: Internal Therapeutic Massager
Class: II (exempt from premarket notification subject to 21 CFR 890.9)
Regulation: 21 CFR 890.5670