DE NOVO CLASSIFICATION REQUEST FOR CEFALY DEVICE

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Transcutaneous Electrical Nerve Stimulator to Treat Headache. A transcutaneous electrical nerve stimulator to treat headache is a device used to apply an electrical current to a patient's cranium through electrodes placed on the skin.

NEW REGULATION NUMBER: 882.5891

CLASSIFICATION: CLASS II

PRODUCT CODE: PCC

BACKGROUND

DEVICE NAME: CEFALY

SUBMISSION NUMBER: K122566

DATE OF DE NOVO: DECEMBER 13, 2012

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REQUESTER'S RECOMMENDED CLASSIFICATION: CLASS II

INDICATIONS FOR USE

The Cefaly device is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.

LIMITATIONS

For prescription use only.

The Cefaly device cannot be used by an individual who has a cardiac pacemaker or an implanted or wearable defibrillator.

The Cefaly device cannot be used by an individual who has an implanted metallic or electronic device in their head.

The Cefaly device should not be used by an individual with chronic migraine, refractory migraine, medication overuse headache, or chronic tension-type headaches. The safety and effectiveness of the device has not been demonstrated for individuals with these conditions.

The Cefaly device should not be applied on the neck or chest, and it should not be used in the presence of electronic monitoring equipment (e.g., cardiac monitors), in the bath or shower, while sleeping, while driving, or while operating machinery.

The long-term effects of using the Cefaly device are unknown.

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

DEVICE DESCRIPTION

The Cefaly device is a transcutaneous electrical nerve stimulator (TENS) that is applied to the forehead (Fig. 1A) using a self-adhesive electrode positioned over the upper branches of the trigeminal nerve bilaterally (Fig. 1B). It is intended to stimulate the upper branches of the trigeminal nerve in order to reduce the frequency of migraine attacks.

A. **B.**

Fig. 1 The components of the Cefaly device and how they are meant to be worn during a treatment session. (A) A subject demonstrating the proper location of the Cefaly device in the middle of the forehead. The Cefaly electrical pulse generator (EPG) is shown and the on/off button can be seen in the middle of the EPG. (B) A drawing that illustrates the proper position of the Cefaly self-adhesive electrode over the supratrochlear and supraorbital branches of the trigeminal nerve. A plastic pin in the middle of the electrode slips into a receptacle on the back of the Cefaly EPG. This attachment is designed to mate the metal contact blades in the back of the Cefaly EPG to the conductive surface of the electrode, and thus transfer the electrical stimulus to the subject during a treatment session.

The Cefaly device consists of two distinct components: an electrical pulse generator (EPG) and a self-adhesive electrode (Fig. 1). The Cefaly EPG (Fig. 1A) is made of ABS plastic and consists of electrical circuits controlled by firmware and powered by two 1.5V batteries. The front of the Cefaly EPG has a single button that is used to turn the device on/off and also to adjust the intensity of the electrical stimulus during a treatment session. Visual and auditory indicators inform the user when the device is on vs. off and help them troubleshoot if it is not working properly (e.g., device indicates if batteries need replacing and if electrical connection between device and skin is unacceptable). The back of the Cefaly EPG has two metal blades that serve to electrically connect it to the Cefaly electrode.

The Cefaly electrode (Fig. 1B) consists of a patient-contacting layer of gel, a layer of silver-coated carbon, and a layer of cotton. An ABS plastic pin in the middle of the electrode fits securely inside a receptacle in the back of the Cefaly EPG in order to maintain a secure electrical connection during a treatment session. The Cefaly electrode is meant to be used only with the Cefaly EPG, and vice versa. It can be reused a maximum of 20 times.

A treatment session begins by attaching the Cefaly electrode to the middle of the forehead and attaching the Cefaly EPG to the electrode. When the on/off button is depressed, a pulsatile electrical stimulus is applied for 20 minutes. During the first 14 minutes, the intensity of the stimulus gradually increases until it reaches a maximum. At any time while the stimulus intensity is increasing, the user can press the button on the front of the device to select an intensity that is lower than the maximum, and it will remain constant at this lower value for the remainder of the treatment session. The device turns the stimulus off automatically after 20 minutes, or alternatively, the user can stop a treatment session by pressing the button twice or simply removing the device from their forehead. The technical characteristics of the Cefaly device are summarized in Tables 1 and 2.

Table 1: Features of the Cefaly device

Power Source	2 AAA alkaline batteries, 1.5V each
Channels	1
Software-controlled	Yes, 1 fixed program
Constant Current	Yes
Automatic overload trip voltage level	Yes
Patient override control method	On/Off button on front of device
Indicator displays: Unit functioning Low battery Electrical connection	 Yes Yes Yes
Timer Setting	Yes
Weight	30 g
Dimensions	160 x 170 x 40 mm

Table 2: Output Specifications for the Cefaly device

Waveform	Biphasic, rectangular, symmetrical
Phase Duration (μsec)	250
Duration between the two phases (μsec)	5
Pulse Duration (μsec)	505
Frequency (Hz)	60
Net Charge (μC) per pulse	0
Maximum output voltage (V): @500 ohms	 8

@2000 ohms @10000 ohms	32 60
Maximum output current (mA): @500 ohms @2000 ohms @10000 ohms	 16 16 6
Maximum phase charge (μC) @500Ω	4
Maximum Current Density, (mA/cm², r.m.s.) @500Ω	2.37
Maximum Average Power Density, (W/cm²) @500Ω	0.000017
Maximum Average Current (average absolute value, mA) @500Ω	0.48

BIOCOMPATIBILITY/MATERIALS

The patient-contacting surface of the Cefaly electrode is Comfort gel A hydrogel – M807 from R&D Medical. The electrode has limited duration contact (< 24 hours) with the intact skin. Therefore, per ISO 10993-1 (Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing), cytotoxicity, sensitization, and irritation testing were performed for the electrode. The testing and results were considered to be adequate.

SHELF LIFE/STERILITY

The Cefaly device is not provided sterile, nor are any of the components to be sterilized by the end user. Cleaning and maintenance instructions for the electrical pulse generator component of the Cefaly device are included in the labeling.

The shelf life of the Cefaly electrode is 30 months and it can be reused 20 times. Testing was provided to support the shelf life and reuse of the electrode, and the data provided was considered to be adequate.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL, MECHANICAL, AND THERMAL SAFETY

The Cefaly device conformed to the following electromagnetic compatibility, electrical, mechanical, and thermal safety standards:

- IEC60601-1: Medical Electrical Equipment; Part 1: General Requirements for Basic Safety and Essential Performance.
- IEC60601-1-2: Medical Electrical Equipment; Part 1-2: General Requirements for Safety – Section 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- IEC60601-2-10: Medical Electrical Equipment; Part 2-10: Particular Requirements for the Safety of Nerve and Muscle Stimulators.

SOFTWARE

The proprietary firmware controls the output of the device and the device indicators. The firmware was reviewed, and the provided documentation was found adequate and consistent with a 'MODERATE' level of concern, as discussed in the FDA document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005.

PERFORMANCE TESTING – BENCH

The sponsor provided thorough bench testing results which were all considered to be adequate. All features and output specifications identified in Tables 1 and 2 for the Cefaly device were verified under various loading conditions meant to simulate those the device could encounter during use.

Bench testing of the Cefaly electrode included verification of the following:

- Shelf life
- Reusability
- Electrical Impedance
- Uniform current distribution
- Adhesive performance

SUMMARY OF CLINICAL INFORMATION

Study 1: PREvention of MIgraine using the STS CEfaly (PREMICE study)

Methods:

The study was a prospective, multicenter, double blinded, randomized, and sham-controlled trial conducted in 5 Belgian tertiary headache clinics run by members of the Belgian Headache Society. The study was approved by the ethics committee of each participating center and written informed consent was obtained from all subjects. Subjects were included if they were between 18 and 65 years old, had migraine attacks with or without aura (International Classification of Headache Disorders (ICHD) – II code 1.2.1 or 1.1), and had at least 2 attacks per month. Subjects were excluded if they had received a preventive antimigraine treatment in the previous 3 months, had refractory migraine (at least 3 failed attempts of well-conducted preventive drug treatments), had chronic migraine, fulfilled criteria for medication overuse headache (ICHD-II 8.2) or frequent/chronic tension-type headache (ICHD-II 2.2/2.3), or had other severe neurological or psychiatric disorders.

Eligible subjects were evaluated for a run-in period of 1 month. After this run-in month, subjects still meeting the inclusion criteria were randomized 1:1 into a verum (treatment) or sham group. Both groups of subjects received the Cefaly device, the same set of instructions regarding how to use the device, and the same user manual. The Cefaly device given to each group of subjects was identical except for the electrical output of the device

during the 20 minute daily treatment session. The differences between the stimuli are shown in Table 3.

Table 3: Electrical Output of Cefaly Device given to Verum Group vs. Sham Group

	Verum Group	Sham Group
Pulse Width (μsec)	250	30
Frequency (Hz)	60	1
Maximum Intensity (mA)	16	1

The 30-day run-in period was followed by a 90-day treatment period with an intermediate office visit after 45 days and a final visit at the end of the trial. Subjects filled in diaries recording headache occurrence and its severity on a 4-point scale (0, no pain; 1, mild—not interfering with normal daily activities; 2, moderate—interfering with daily activities; 3, severe pain—prohibiting daily activities), presence of an aura, nausea/vomiting, phonophobia or photophobia, and acute antimigraine drug intake. A migraine day was defined as a day with headache fulfilling ICHD-II criteria for migraine, except for duration if treated. Migraine days not separated by at least one headache-free day were considered to belong to the same migraine attack. A headache of grade 1 severity without associated symptoms and not treated with an acute medication was recorded as "headache," not migraine.

Primary outcome measures were the following:

- Change in monthly migraine days between the run-in month and the third month of treatment.
- Percentage of "responders", i.e., of subjects having at least a 50% reduction of monthly migraine days between the run-in month and the third month of treatment.

Secondary outcome measures were the following:

- Change in monthly migraine days between the run-in month and the average for the 3 months of treatment.
- Change in monthly migraine attack frequency.
- Change in monthly frequency of any headache.
- Change in mean headache severity per migraine day.
- Change in monthly acute anti-migraine drug use and in associated symptoms per migraine headache between the run-in month and the third month of treatment.
- Percentage of subjects stating at the end of the trial that they are very satisfied, moderately satisfied, or not satisfied with the treatment.

Sample size calculations were based on responder rates obtained from a combination of published studies and pilot work. A responder rate of 15% was assumed for the sham group and 55% for the verum group. To detect a significant difference between the 2 groups (5% significance level) with 80% power, the minimum size of each group was estimated at 26 subjects.

Statistical analysis (R, The R Foundation for Statistical Computing) was carried out on an intent-to- treat basis. Values for subjects who dropped out were included according to the last value carried forward method. The Mann-Whitney U test was used for comparison of primary and secondary outcome measures between the verum and sham groups, Fisher's two-tailed exact test for responder rates and the sign test for changes between the run-in month and the third month of treatment/average of the 3 months of treatment within sham and verum groups.

Results:

A total of 67 subjects were randomized, and 59 completed the study according to the protocol (Table 4). The intent-to-treat population is all randomized subjects. The per protocol population is all subjects who completed the three month treatment period and filled in their migraine diary appropriately (4 subjects from each group were excluded from the per protocol analysis). There were no significant demographic differences between the treatment and sham groups. There was no significant difference in treatment effect between subjects experiencing exclusively migraine without aura and those having both migraine types.

Table 4: Subject disposition, age and gender distribution per group.

	Intent-to-treat			**Per protocol**		
	Verum	**Sham**	**All**	**Verum**	**Sham**	**All**
n	**34**	**33**	**67**	**30**	**29**	**59**
Age	34.59 ±11.01	39.06 ±9.87	36.79 ±10.63	33.27 ±10.21	38.97 ±9.43	36.07 ±10.16
Sex						
Male	3(9)	3(9)	6(9)	3(10)	3(10)	6(10)
Female	31 (91)	30(91)	61(91)	30(90)	29(90)	59(90)
Occasionally Migraine with aura	10	10	20	9	8	17
Exclusively Migraine Without aura	24	23	47	21	21	42

Data are expressed as n(%) or mean ± SD.

No serious adverse events occurred during the trial in either group of subjects. One subject reported at the Day 45 office visit that the device caused a headache and that they decided to exit the trial. No adverse device events or unanticipated device reports occurred during the trial.

The number and duration of treatment sessions with the Cefaly device were recorded electronically by the device and read out at the end of the trial. The subjects were instructed to use the device daily over the 3 month treatment period. However, instead of 90 stimulation sessions, the mean number of sessions was 55.54 in the verum group and

49 in the sham group. The difference between the two groups was not statistically significant.

In both the verum and sham groups, migraine days decreased by an average of 20% during the first month of treatment (Fig. 2). Over the second and third month of the treatment period, this decrease grew larger in the verum group whereas for the sham group, the number of migraine days approached that observed during the run-in month.

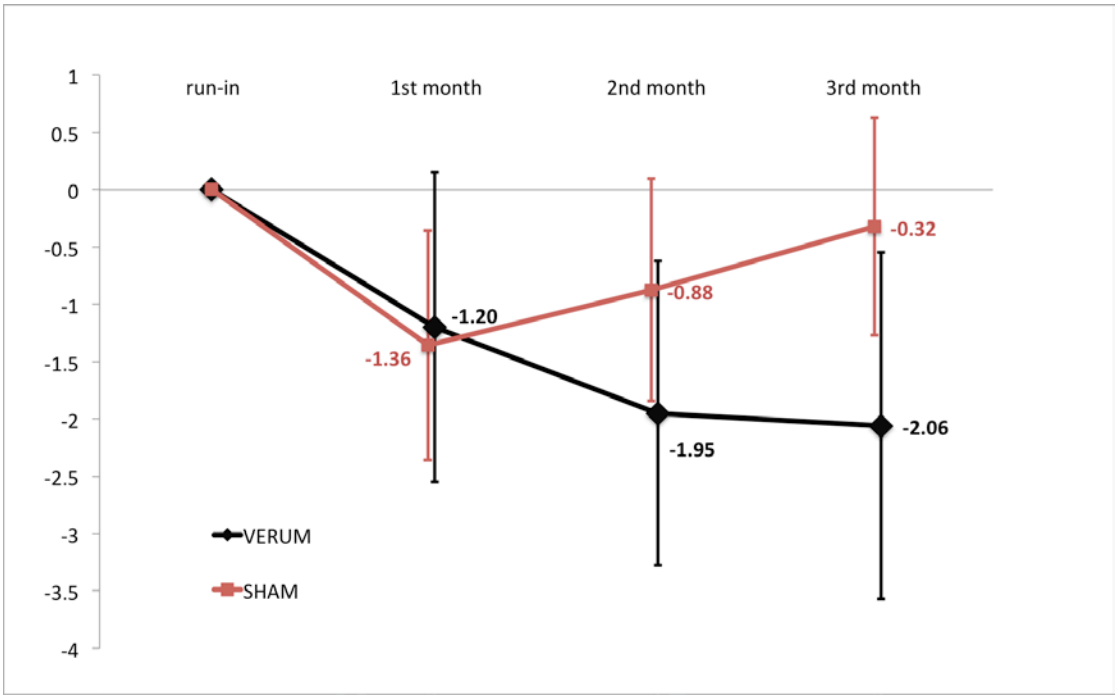

Fig. 2 Change in the number of migraine days during the treatment period, relative to the 1-month run-in period. For each group, the average change and confidence interval is shown for each month during the treatment period.

The results of the PREMICE study are summarized in Table 5. A baseline-observation-carried-forward analysis was performed to assess the effect of missing data for the intent-to-treat population, and there were only minor changes to the results that have no impact on the overall conclusions of the study.

Table 5: Primary and secondary outcomes of the trial broken down by analyses and treatment group (mean±standard deviation or percentage of subjects (number of subjects)).

A. Migraine days (run-in compared to 3rd month of treatment)				
	Intention-to-treat		Per protocol	
	Verum	Sham	Verum	Sham
Migraine days run-in month	6.94±3.04	6.54±2.61	6.90±3.18	6.60±2.72
Migraine days 3rd month	4.88±3.46	6.22±2.99	4.81±3.54	6.25±3.14
Change from run-in to 3rd month in each group	p=0.023	p=0.608	p=0.032	p=0.648
Comparison between the two groups	p=0.08		p=0.098	
B. Percentage of responders ≥50% reduction in number of migraine days/month) and of subjects with at least moderate improvement ≥ 25% reduction in number of migraine days/month)				
Responders (≥50% reduction)	38.2% (13)	12.1% (4)	40.0% (12)	13.8% (4)
Comparison between the groups	p=0.023		p=0.039	
Subjects with at least moderate improvement ≥25% reduction)	58.8% (20)	27.3% (9)	63.3% (19)	31.0 (9)
Comparison between the two groups	p=0.014		p=0.019	
C. Migraine days (run-in month compared to average of the 3-month randomized treatment period)				
Migraine days run-in month	6.94±3.04	6.54±2.61	6.90±3.18	6.60±2.72
Migraine days mean of the 3 months of treatment	5.20±2.99	5.68±2.60	5.08±3.06	5.65±2.72
Change from run-in to the average of 3 months of treatment within each group	p=0.023	p=0.082	p=0.017	p=0.093
Comparison between the two groups	p=0.366		p=0.367	
D. Migraine attacks				
Migraine attacks run-in month	4.37±1.87	4.04±1.52	4.33±1.95	3.87±1.51
Migraine attacks 3rd month	3.55±2.94	3.89±1.89	3.40±2.96	3.86±1.97
Change from run-in to·3rd month in each group	p=0.058	p=0.516	p=0.043	P=0.819
Comparison between the two groups	p=0.044		p=0.028	
E. Headache days				
Total headache days run-in month	7.78±4.00	6.72±2.63	7.85±4.21	6.74±2.68
Total headache days 3rd month	5.27±3.55	6.49±3.20	5.22±3.62	6.56±3.36
Change from run-in to 3rd month in each group	p=0.011	p=0.674	p=0.015	p=0.859
Comparison between the two groups	p=0.041		p=0.041	
F. Severity of migraine days				
Migraine severity run-in month	1.96±0.46	1.78±0.41	1.99±0.44	1.82±0.39
Migraine severity 3rd month	1.80±0.60	1.73±0.53	1.78±0.59	1.73±0.55
Change from run-in to 3rd month in each group	p=0.131	p=0.443	p=0.057	p=0.287
Comparison between the two groups	p=0.301		p=0.274	
G. Acute anti-migraine drug intake				
	Intent to Treat		50% responders	
	Verum	Sham	Verum	
Acute anti-migraine drugs taken in run-in month	11.45±8.35	9.24±4.75	12.85±10.79	
Acute anti-migraine drugs taken in 3rd	7.25±7.31	9.28±5.69	3.27±3.79	

month				
Change from run-in to 3rd month in each group	p=0.0057	p=0.822	p=0.0017	
Comparison between the two groups	p=0.0072			
H. Subjects' satisfaction after 3 months of treatment				
	Very Satisfied	Moderately satisfied	Not at all satisfied	Not available
Verum (34)	29.4% (10)	41.2% (14)	21.2% (7)	8.8% (3)
Sham (33)	18.2% (6)	21.2% (7)	51.5% (17)	9.1% (3)

Co-Primary Endpoints

Results for the primary outcome measures are shown in Table 5A and 5B. The responder rate was 38.2% in the verum group vs. 12.1% in the sham group and this difference was statistically significant ($p < 0.025$). Monthly migraine days decreased more in the verum group (-2.06) than in the sham group (-0.32) but this difference was not statistically significant. Improvement in monthly migraine days was observed to be greater for patients having more than 6 migraine attacks per month at baseline compared to patients having fewer than 6 attacks per month at baseline.

Secondary Endpoints

Results for the secondary outcome measures are shown in Table 5C – G. The monthly intake of acute anti-migraine drugs (Table 5G) decreased by 36.6% in the verum group and by only 0.5% in the sham group, and this difference between groups was statistically significant even when adjusted for multiplicity ($p<0.01$). In the subgroup of responders within the verum group, the monthly drug intake decreased by 74.55%.

Monthly migraine days for the verum group gradually decreased during the treatment period (Fig. 2); therefore, the reduction in monthly migraine days is less pronounced when comparing the 1-month run-in to the average of the 3-month treatment period (-1.74, Table 5C) vs. when comparing the 1-month run-in to the third month of the treatment period (-2.06, Table 5A). Nevertheless, the reduction between run-in and the average of the 3-month treatment period within the verum group approaches significance.

Between the 1-month run-in and the third month of treatment, monthly migraine attack frequency (Table 5D) was reduced by 0.82 (18.8%) in the verum group and by 0.14 (3.5%) in the sham group. This difference is more pronounced in the per protocol analysis showing a 21.5% reduction in the verum group vs. 0.26% in the sham group. Monthly days with any headache (Table 5C) was reduced by 2.55 (32.7%) in the verum group but only 0.28 (4.1%) in the sham group. However, the differences observed between the two groups are not significant when adjusted for multiplicity.

There was no significant change in the mean headache severity per migraine day after 3 months of treatment (Table 5G).

When asked to rate their satisfaction with the treatment at the end of the trial, 24 out of 34 subjects (70.6%) in the verum group responded that they were very satisfied or moderately satisfied. When the same question was posed to subjects in the sham group, 13 of 33 (39%) responded that they were very satisfied or moderately satisfied with the treatment.

Study 2: European Post-Marketing Surveillance Study

A prospective registry was established of all consecutive patients, mainly located in France and Belgium, who obtained the Cefaly device between September 2009 and June 2012. The STX-Med consumer service and medical department conducted a survey of the 2,313 patients after they had used the device for between 40 and 80 days. Patients were asked if they were satisfied with the Cefaly device and if they had any side effects and/or complaints after using the device.

This study showed that a little more than 53 percent of patients were satisfied with Cefaly treatment and willing to continue using the device. Ninety-nine subjects (4.3%) had one or more complaints, but none of them were serious adverse events and all were fully reversible. The most commonly reported complaints were disliked the feeling during treatment and did not want to continue using the device (2%), sleepiness during the treatment session (<1%), and headache after the treatment session (<1%).

LABELING

The *Cefaly Instructions for Use* are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact use of the device. The labeling is sufficient and satisfies the requirements of 21 CFR § 801.109 Prescription devices.

RISKS TO HEALTH

Table 7 identifies the risks to health that may be associated with the use of a Transcutaneous Electrical Nerve Stimulator to Treat Headache and the measures necessary to mitigate these risks.

Table 7: Risk/Mitigation Measures

Identified Risk	Mitigation Measures
Adverse Reactions to skin-contacting materials	Biocompatibility Testing Labeling
Electrical, Mechanical, or Thermal Hazards that may result in user discomfort or injury	Electromagnetic Compatibility Testing Electrical, Mechanical, and Thermal Safety Testing Technical Parameters Electrode Performance Testing Software Verification, Validation and Hazard Analysis Labeling
Ineffective treatment	Clinical Performance Data Labeling
Failure to identify the correct population	Clinical Performance Data Labeling
Misuse that may result in user discomfort, injury, or delay treatment for headaches	Labeling

SPECIAL CONTROLS:

In combination with the general controls of the Food Drug & Cosmetic Act, the Transcutaneous Electrical Nerve Stimulator to Treat Headache is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. Appropriate analysis/testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.

3. The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2000, and 10000 ohm loads), pulse duration, frequency, net charge (μC) per pulse, maximum phase charge at 500 ohms, maximum current density (mA/cm², r.m.s.), maximum average current (mA), maximum average power density (W/cm²), and the type of impedance monitoring system must be fully characterized.

4. Electrical performance, adhesive integrity, shelf-life, reusability, and current distribution testing of the electrodes must be conducted.

5. Appropriate software verification, validation, and hazard analysis must be performed.

6. Clinical performance data must demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population.

7. Labeling must include the following:
    a. Appropriate contraindications such as not for use in subjects with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator.
    b. Appropriate warnings such as not to apply the device on the neck or chest, not to use the device in the presence of electronic monitoring equipment, not to use in the bath or shower, not to use while sleeping, not to use while driving, not to use while operating machinery.
    c. Appropriate precautions such as the long-term effects of chronic use of the device are unknown.
    d. A summary of the expected risks and benefits of using the device.
    e. A summary of the clinical performance data, including information on the patient population for which the device has and has not been demonstrated to be effective, and any adverse events and complications.
    f. Information on how the device operates and the typical sensations experienced during treatment.
    g. A detailed summary of the device technical parameters.
    h. An expiration date/shelf life for the electrodes and the number of times they can be reused.
    i. Disposal instructions.

BENEFIT/RISK DETERMINATION

The risks of the device are based on data collected in the randomized controlled clinical study and the observational post-marketing surveillance study. There were no serious adverse events reported in either study and all adverse events were minor and reversible. Based on this information, the risks associated with use of the Cefaly device for the prevention of migraines are considered low.

The probable benefits of the device are based on data collected in the randomized controlled clinical study, which demonstrated that a significant percentage of subjects responded to treatment with a clinically relevant reduction in migraine days per month. The study also demonstrated a clinically relevant reduction in the amount of anti-migraine medications taken by patients treated with the device. One of the two primary effectiveness endpoints (reduction in migraine days) and some of the secondary endpoints (e.g., migraine attack frequency) failed to achieve statistical significance when comparisons were made between groups; however, the trends observed for these endpoints also suggested a probable benefit. In addition, more than half of the patients in the randomized controlled clinical study and the post-marketing surveillance study reported that they were at least moderately satisfied with the treatment and willing to continue using the Cefaly device. Although data for patients in the transitional age group from 18 to 22 years are limited, the performance of the Cefaly device is not expected to be different for this group when compared to that of adults 22 years of age and over.

Additional factors to be considered in determining probable risks and benefits for the Cefaly device include: (1) a randomized, double blinded, multi-site, sham-controlled clinical trial was provided to evaluate risks and benefits (2) Medications that are approved for migraine prevention produce similar benefits to those obtained when using the Cefaly device (i.e., reduction in monthly migraine days of 1 or 2 per month); however, these medications can produce problematic side effects such as cognitive changes.

In conclusion, the data support that for a transcutaneous electrical nerve stimulator to treat headache that is intended to be used for the prophylactic treatment of episodic migraine in patients 18 years of age or older, the probable benefits outweigh the probable risks. The Cefaly device provides benefits and the risks can be mitigated by the use of general and special controls.

CONCLUSION

The *de novo* for the Cefaly device is granted and the device is classified under the following:

Product Code: PCC
Device Type: Transcutaneous Electrical Nerve Stimulator to Treat Headache
Class: Class II
Regulation: 21 CFR 882.5891