

# Letters From People Who Use Alpha-Stim for Themselves



# PUBLIC SUBMISSION

<b>As of:</b> 10/14/11 9:01 AM <b>Tracking No.</b> 80f4c840 <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0070](#)

Beverly C Babcock - Comment

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## Submitter Information

**Address:**

CA,

**Organization:** retired

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## General Comment

My husband (Charles Stern) deceased--pancreatic & prostate cancer--used Cranial Electrotherapy Stimulator to relieve chronic physical discomfort, anxiety & stress. Quite effective.

I, too, then and now, use CES ti relieve stress; very helpful.

# PUBLIC SUBMISSION

As of: 10/14/11 9:13 AM  
Tracking No. 80f4ab37  
Comments Due: November 07, 2011

**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0064](#)

Bryan Keith Thomason - Comment

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## Submitter Information

**Address:**

OK,

**Organization:** Electromedical Products international, Inc

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## General Comment

October 3, 2011  
Nancy K. Stade  
Deputy Director for Policy,  
Center for Devices and Radiological Health  
Food and Drug Administration  
5630 Fisher Lane, Room 1061  
Rockville, Maryland 20852

Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule: "Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator." [Docket No. FDA-2011-N-0504].

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the Federal Register on August 8, 2011 (76 F.R. 152, p. 48062). As a consumer who owns an Alpha-Stim, I wanted to share with FDA my own findings on the device.

I have degenerative disc disease in my neck which produces a considerable amount of pain induced anxiety. I have used my Alpha-Stim at least once daily since I purchased it over a year ago and it has enabled me to reduce the amount of anxiety medication I take by over 75%. I feel that using the Alpha-Stim as part of my pain management regimen is very beneficial.

Thank you for your attention to this matter. It is my hope that FDA will allow CES to be down-classified to a Class II device.

Sincerely,

Bryan K. Thomason  
1416 N.W. 187th Street  
Edmond, OK 73012  
E-Mail: [SovereignTitleOK@aol.com](mailto:SovereignTitleOK@aol.com)

# PUBLIC SUBMISSION

<b>As of:</b> 10/14/11 9:10 AM <b>Tracking No.</b> 80f4ac84 <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0066](#)

carol noriko harlos - Comment

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## Submitter Information

**Address:**

TX,

**Organization:** self

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## General Comment

I have used the Alpha Stim off and on for several years. I have had no adverse effects from its use, and in general I feel like it has been beneficial to me in helping with anxiety and depression issues I have faced. I feel like it generally "evens out" my mind and brings a sense of calmness and quiet to me. Usually, I would use it while meditating or while journal writing, and found the combination of these activities brought positive results for me. I missed it if I didn't do these activities in the morning.

Oct. 3, 2011

Nancy K. Stade  
Deputy Director for Policy,  
Center for Devices and Radiological Health  
Food and Drug Administration  
5630 Fisher Lane, Room 1061  
Rockville, Maryland 20852

**Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule:  
“Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy  
Stimulator.” [Docket No. FDA-2011-N-0504].**

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the *Federal Register* on August 8, 2011 (76 F.R. 152, p. 48062). As a consumer who owns an Alpha-Stim, I wanted to share with FDA my own findings on the device.

As a Vietnam Veteran with PTSD I find that the use of my Alpha-Stim helps to ease my anxiety and allows me to rest better during the night. I also get at least 15 minutes of restful sleep when I use my Alpha-Stim. It has also decreased the pain that I had in both of my hands. My wife even comments that I seem to be more relaxed and not so uptight after a session with the Alpha-Stim.

Thank you for your attention to this matter. It is my hope that FDA will allow CES to be down-classified to a Class II device.

Sincerely,

Elmer W. Hunter

5217 Campcreek LP

Roseville, CA 95747

golfnuteh1@comcast.net

Mrs. Fran Ekelund

6 Redbay Ct. West

Homosassa, FL 34446

Page 1 of 2 Pages

August 23, 2011

Ms. Nancy K. Stade  
Deputy Director for Policy,  
Center for Devices and Radiological Health  
Food and Drug Administration  
5630 Fisher Lane, Room 1061  
Rockville, Maryland 20852

**Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule:  
“Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy  
Stimulator.” [Docket No. FDA-2011-N-0504].**

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the *Federal Register* on August 8, 2011 (76 F.R. 152, p. 48062). I am retired and have been hurt in a car accident. I had the trunk of a Kia slammed on my head while I was adjusting my luggage that had fallen over. The gentlemen who picked me up from the airport hadn't seen me bend in to re-adjust my suitcases. I have been dealing with a lot of pain and muscle spasms in my head and neck. The pain was extreme and after a few visits with my doctor, he treated me with an Alpha Stim 100 in his office. I had gotten a lot of bad results from taking medication and nothing seemed to work. Chiropractic treatment did not work. After my first treatment with the Alpha Stim 100, I felt considerable lessening of my pain. The Alpha Stim 100 has helped also getting me to sleep better at night with less anxiety. I am able to manage my pain with this Alpha Stim 100 that I rented and have now purchased. I am retired and this has saved me from a lot of expensive doctor appointments for treatments and has also enabled me not to take medications that would affect my body with negative health issues. The Alpha stem has improved my quality life. I am able to use it for my pain management. I feel CES is very safe with a lot of benefits. My doctor also is able to answer any questions I may have in my treatment with the Alpha Stim 100. I'm on social security and I could not afford going to the doctors constantly and taking medications that would make me sick in the long run.

I also feel the military personnel and veterans have a right to be able to get these machines in the United States of America. WE NEED TO BE HEARD AND HAVE A VOICE IN THIS MATTER.

Page 2 of 2 Pages

Ms. Nancy K. Stade – Docket No. FDA-2011-N-0504

Thank you for your attention to this matter. It is my hope that FDA will allow CES to be down-classified to a Class II device as it has proven itself to be both safe and effective. Thank you for this consideration and I wish to be heard and a voice for all those people needing this device. To be able to purchase it in the United States is also very important to me.

Sincerely,

Fran Ekelund, Retired

Homemaker

(352) 382-3718

The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule: "Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator." [Docket No. FDA-2011-N-0504].

November 5, 2011

Nancy K. Stade  
Deputy Director for Policy, Center for Devices and Radiological Health  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: **Docket No. FDA-2011-N-0504 – Please post for public viewing**

Dear Ms. Stade:

Please do not take Alpha-Stim cranial electrotherapy stimulation (CES) off the market! It would be a great disservice to those individuals who are seeking an alternative to drugs which have serious side-effects. I have used Alpha-Stim CES for over two years for anxiety and stress and have found it very effective and safe. Daily treatments with Alpha-Stim CES enabled me to function after my son, an orthopedic surgeon, had a devastating ATV accident while setting up a deer blind in a hilly wooded area on his ranch. He was pinned under the platform of the ATV (where you put hay and feed for animals) for 20 hours before anyone found him. He was in a coma for five weeks, in ICU in very critical condition for over two months and in a rehab hospital for two months. He had fourteen surgeries and over 200 units of blood. In addition to multiple fractures and cuts, his right leg was amputated above the knee. While the trauma team was able to save his left leg, it is basically useless and my son will most likely decide to have it amputated as well. He also has kidney damage which will require additional surgery. Today he has progressed to where he can be up 2 – 3 hours at a time. He can take a few steps with a walker, but he is mostly confined to a wheel chair.

I cannot begin to tell you the anguish, grief, anxiety and stress I have had over my son's accident. Using Alpha-Stim CES enabled me function and to be there for my son. I respectfully request that you down-classify Alpha-Stim CES to Class II.

Sincerely,



Frances Wood  
10727 Villager Rd  
Dallas, TX 75230

# PUBLIC SUBMISSION

<b>As of:</b> 10/14/11 9:11 AM <b>Tracking No.</b> 80f486c4 <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0063](#)

Gail Bliss Moore - Comment

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## Submitter Information

**Address:**

CA,

**Submitter's Representative:** self

**Organization:** I am not affiliated with an organization

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## General Comment

I find this device enormously effective in treating my own occasional insomnia, which stems from a unregularised work schedule and thus my inability to go to sleep and wake up at the same times. I care for people who are either terminally ill or elderly, and have heard from the two I currently work with that this device is very effective for depression as well, though I haven't used it for that on myself. Given that ill and/or elderly people frequently suffer from depression, and that adding an oral antidepressant to the medications they are already taken is often not a good idea, this has made a measurable difference in the moods of my clients, and has enabled them to enjoy their lives more fully without their having to take additional medication. I and they are very happy with the non-invasive and entirely benign effects of this treatment, and I can recommend it highly.

# PUBLIC SUBMISSION

<b>As of:</b> 11/8/11 12:28 PM <b>Tracking No.</b> 80f53b07 <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0100](#)

Gerald Raynold Pratt - Comment

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## Submitter Information

**Address:**

OK,

**Submitter's Representative:** N/a

**Organization:** None...Personal

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## General Comment

To Whomever;

I would like everyone to know that without my Alpha-Stim I would be a quivering bowl of pain...mental and physical. I also take Prozac, Methadone, Flexeril, Oxycodone, and others. My Alpha-Stim unit is as effective as one of my Methadone pills and helps in the chronic depression and muscle spasms that I have on a minute-to-minute basis. At times it can even "fill in" for some of these meds. AND it is not addictive in any way.

You may always call me for more info. My phone number is: Home 580 2-1862; Cell 580 402-5206. My home mail address is: 623 W. Illinois Ave., Enid, Oklahoma 73701.

Thank You for your concern

Gerald (Gerry) Pratt

November 6, 2011

Nancy K. Stade  
Deputy Director for Policy, Center for Devices and Radiological Health  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: **Docket No. FDA-2011-N-0504 - Please post for public viewing**

Dear Ms. Stade:

I am writing in response to your request for comments about Alpha-Stim. My dad, Rex Hensley, used Alpha-Stim CES for anxiety for five years. His sister who cared for him while he had a stem cell transplant for non-Hodgkin's lymphoma, bought Dad an Alpha-Stim CES unit. He used it daily while he was getting the high-dose chemo in preparation for the transplant and 2 - 3 times a day when he became anxious after the transplant. His anxiety would lessen while using Alpha-Stim and he would fall asleep. My dad recently died from pulmonary fibrosis. His air hunger increased his anxiety and panic attacks. Alpha-Stim was a Godsend, his anxiety seemed to melt away and he would fall asleep. Dad used Alpha-Stim even when he was receiving Hospice care. His sister bought him another Alpha-Stim CES unit, so that he could keep one next to his bed and one next to his Lazy Boy chair in the living room. Alpha-Stim made my Dad's last days more bearable. Those of us who loved him so dearly were so thankful for the relief he obtained from Alpha-Stim.

Please down classify Alpha-Stim CES to Class II. It is safe and effective especially when compared to drugs which have dangerous side effects.

Thank you.

*Jana Best*

Jana Best  
12338 SW Mockingbird Rd  
Andover, KS 67002

September 30, 2011

Nancy K. Stade  
Deputy Director for Policy,  
Center for Devices and Radiological Health  
Food and Drug Administration  
5630 Fisher Lane, Room 1061  
Rockville, Maryland 20852

**Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule:  
“Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy  
Stimulator.” [Docket No. FDA-2011-N-0504].**

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the *Federal Register* on August 8, 2011 (76 F.R. 152, p. 48062). As a consumer who owns an Alpha-Stim, I wanted to share with FDA my own findings on the device.

I suffer from a rare genetic disorder (Ehrlers-Danlos Syndrome, EDS, a disease of collagen formation) that leaves me in constant unremitting full body writhing pain. I have tried every substance and therapy known to man and woman to deal with this high level of constant pain that effects my daily life and everything I attempt to do. You name it, I've tried it many times. The only thing that helps me control the constant pain is my micro-current unit made by Alpha-Stim which was recommended to me by my physical therapist. I have been using it for just under 5 years and I am actually scared to even consider living without it. It has helped me IMMENSELY. I urge you to please approve this product which has literally saved my life because without I would have already committed suicide from the constant unremitting pain I am forced to live with.

Thank you for your attention to this matter. It is my hope that FDA will allow CES to be down-classified to a Class II device.

Sincerely,

Janet Ehrlich  
12923 Warren Ave.  
Los Angeles, CA 90066  
310-398-8062  
luckydogsangel@gmail.com

1 November 2011

Nancy K. Stade  
Deputy Director for Policy,  
Center for Devices and Radiological Health  
Food and Drug Administration  
5630 Fisher Lane, Room 1061  
Rockville, Maryland 20852

**Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule: “Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator.” [Docket No. FDA-2011-N-0504].**

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the *Federal Register* on August 8, 2011 (76 F.R. 152, p. 48062). As a Nurse who uses CES personally, I wanted to share with FDA my own findings on the efficacy and safety of CES.

Being a Nursing Supervisor, I deal with many stressful situations. I experience headaches, back and neck pain on nearly a daily basis. The Alpha-Stim has been a valuable adjunct therapy for relief of pain and headaches due to stress, arthritis and fibromyalgia. The Alpha-Stim is safe and effective; I have never experienced any untoward effects in the 3 years that I have been using it.

Thank you for your attention to this matter. It is my hope that FDA will allow CES to be down-classified to a Class II device as it has proven itself to be both safe and effective.

Sincerely,

Jo Anne McElligott, RN, MSN  
Colonel (Ret), US Army Nurse Corps  
Nursing Supervisor, Landstuhl Regional Medical Center  
Landstuhl, Germany

# PUBLIC SUBMISSION

<b>As of:</b> 11/8/11 12:03 PM <b>Tracking No.</b> 80f51488 <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0088](#)

Juliana Roberta Sacilotto - Comment

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## Submitter Information

**Address:**

VA,

**Submitter's Representative:** Dr Alan Spector

**Organization:** Virginia neurotherapy

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## General Comment

I have used the Alpha-stim device on a daily basis since April 2009 for anxiety and depression and it has significantly decreased both of them. This has allowed me to think clearly and make sound judgements. I have been able to be continue to work full time because of it. It has decreased my migraine headaches significantly and I used it in conjunction with neurofeedback therapies on a weekly basis with Dr. Spector.

# PUBLIC SUBMISSION

<b>As of:</b> 10/14/11 9:08 AM <b>Tracking No.</b> 80f4ff36 <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0075](#)

Karen Ellen Evans - Comment

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## Submitter Information

**Address:**

MO,

**Organization:** Dr. Don Brady

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## General Comment

I use the Cranial Electronic Stimulus (CES) to enhance my therapy for PTSD, anxiety, and depression. I use the CES once a day for an hour and twice a day if necessary.

The benefit I receive from the CES includes the calming of my mind enough to have a regular sleep pattern; plus it allows for a more productive therapy session as my therapist and I do not have to spend time in my session lowering my anxiety.

If I have issues between therapy sessions with nightmares usage of the CES decreases the intensity of those allow an improved sleep pattern.

My faith and ownership of the CES are key factors in my moving forward in my therapy.

# PUBLIC SUBMISSION

<b>As of:</b> 10/14/11 9:09 AM <b>Tracking No.</b> 80f4bb6b <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0069](#)

Owen Duff Beall - Comment

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## Submitter Information

**Address:**

NY,

**Organization:** self

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## General Comment

Hello.

I had no ill effects from the use of this CES machine whatsoever. (alpha-Stim)

I am not sure what the purpose of this proceeding is, but I am totally opposed to any FDA prohibition of such devices.

People own their own bodies and their brains. One's body and brain are not owned by pharmaceutical companies.

What is needed in this country is the separation of medicine and state (as in separation of church and state).

Why should a person be prohibited from using his freedom to directly explore the process of his own health?? And in the process, using devices that enhance the functioning of biological processes that are already at work in the body and brain??

As opposed to being forced to use pharmaceuticals that introduce dangerous effects and "side-effects"??

thank you.

Owen Beall

# PUBLIC SUBMISSION

<b>As of:</b> 11/8/11 12:00 PM <b>Tracking No.</b> 80f5418b <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0104](#)

Paula Annette Rodriguez - Comment

## Submitter Information

**Address:**

TX,

**Organization:** Rn

## General Comment

October 17, 2011

Nancy K. Stade

Deputy Director for Policy,

Center for Devices and Radiological Health

Food and Drug Administration

5630 Fisher Lane, Room 1061

Rockville, Maryland 20852

Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule: "Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator." [Docket No. FDA-2011-N-0504].

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the Federal Register on August 8, 2011 (76 F.R. 152, p. 48062). As a practitioner who uses CES in my practice, I wanted to share with FDA my own findings on the efficacy and safety of CES.

I am writing a personal testimony of the effectiveness of the alpha stim for pain control. My Mother Murlene Tice was diagnosed with primary liver cancer. She was able to use this device exclusively for pain control. She was unable to take narcotics because they caused hallucinations, but the device not only controlled her pain but allowed her to have a clear alert mental status up until the time of her death. I will be forever grateful.

Thank you for your attention to this matter. It is my hope that FDA will allow CES to be down-classified to a Class II device as it has proven itself to be both safe and effective.

Sincerely,

Paula Rodriguez RN

# PUBLIC SUBMISSION

<b>As of:</b> 10/14/11 9:09 AM <b>Tracking No.</b> 80f4f5f1 <b>Comments Due:</b> November 07, 2011
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**Docket:** [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Comment On:** [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

**Document:** [FDA-2011-N-0504-0073](#)

Z. Vogt - Comment

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## Submitter Information

**Address:** MO,

**Organization:** health

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## General Comment

My disabled 23 year old daughter has been using the device for 6 months. She has an incurable neurodegenerative disease and is suffering from depression, psychosis, dementia, anxiety and unable to sleep. This device is the closet thing to a miracle. we use it around the clock very 4-6 hours. While she was hospitalized for the past 36 days the Alpha Stim would help with her agitation and calm her. it hepled her relax and sleep better. With in 10 minutes it would stop her hysterical crying. This has been witnessed by dozens of strangers and family on how fast she responds to it. I can think of numerous persons I have recommended that they talk to their doctor about using this device.

