June 17, 2019

John Choate
% Christopher J. Martin, Esq.
The C.J. Martin Law Group
One Research Court, Suite 450
Rockville, Maryland 20850

Re: K162706
Finger Relief Interossei Lumbricals Neuromuscular Technology Interface Therapy Device
Request for Supervisory Review
Date: March 29, 2019
Received: April 2, 2019

Dear Christopher J. Martin:

I have completed the review of your request ("the Company") *** [for] the Division of Neurological and Physical Medicine Devices ("DNPMD" or "the Division"). This letter reflects the findings of my review on behalf of CDRH's Office of Product Evaluation and Quality (OPEQ).

Background

*** Finger Relief Interossei Lumbricals Neuromuscular Technology Interface Therapy Device ("Finger Relief" or "the device"). ***

Finger Relief is a class II, 510(k)-exempt device under 21 CFR 890.3710 (Powered communication system) when intended for use by persons unable to use normal communication methods because of physical impairment. Carpal tunnel syndrome (CTS) is a form of physical impairment. Therefore, a premarket notification is not required to market the Finger Relief for an intended use that is consistent with 21 CFR 890.3710.

Discussion

Finger Relief is a specialized keyboard that allows users to type without unnecessarily over-extending the tendons in their fingers and wrists.1 The indications for use for which clearance was sought in K162706 states, in part, the following:

"The Finger Relief Interossei Lumbricals Neuromuscular Technology Interface Therapy Device is indicated for type communication through a powered device, and is specifically designed to assist those with Carpal Tunnel Syndrome (CTS) to perform all of the tasks associated with typed communication, both in work and leisure. ***

[Facsimile edited for length and relevancy. © Proprietary Disclosure by privacy release only.]
The Device, through its patented modified layout, delays or prolongs the onset of symptoms and reduces the severity of symptoms, for users with CTS (i.e. pain, numbness and tingling), allowing them to perform typing tasks for longer periods of time, and accordingly affording them greater productivity in their lives…

Use of the Device is not related to time or length but is related to physical perception of cues of fatigue (or symptoms of nerve compromise), such as pain, tingling, or numbness. It is recommended that medications that would block pain sensation not be used while typing with the Device. If an individual is using the Finger Relief interossei lumbricals neuromuscular technology interface therapy device and begins to experience pain, tingling, or numbness, he or she should stop using the device until the pain, tingling, or numbness has subsided, usually overnight. There are no contraindications for pregnancy, children, or comorbidities including arthritis or victims of burns."2

In addition, the proposed K162706 labeling included several claims for Finger Relief, including but not limited to prolonging the quality of life, loss of ability of fingers to floss teeth, need for pain relieving drugs, risk of allergic reaction, risk of invasive treatments, and onset of disability.3

*** • The Company is not claiming that the Finger Relief can cure CTS, but rather that the Finger Relief will allow those who suffer from CTS to use the device for longer periods of time than QWERTY before the onset of symptoms of CTS.

• The Pittsburg study supports the Company's assertion that the Finger Relief, designed expressly to minimize the distance traveled by a typist's fingers, reduces the compression of the median nerve and the distance traveled by the fingers of the typist.
***
You clarified that the Company is fundamentally seeking an indications for use in delaying or prolonging the onset of symptoms and reducing the severity of symptoms of CTS, and stated that you would be willing to submit a different indications for use than the one provided in your 510(k) submission.

Based on the information provided, I have found that:
1) *** a premarket notification is not required to market the Finger Relief for an intended use that is consistent with 21 CFR 890.3710. ***

According to 21 CFR 890.3710(a), a powered communication system "…is an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment. Examples of powered communication systems include the following: a specialized typewriter, a reading machine, and a video picture and word screen."

21 CFR 890.3710(b) states that a powered communication system is a Class II device that is exempt6 from the premarket notification procedures in subpart E of 21 CFR 807, subject to the limitations in 21 CFR 890.9. As discussed in 21 CFR 890.9, a powered communication system exceeds the limitations of the exemption when the device "…is intended for a use different from the intended use of a legally marketed device in that generic type of device…" or "…operates

[Facsimile edited for length and relevancy. © Proprietary Disclosure by privacy release only.]
using a different fundamental scientific technology than a legally marketed device in that generic type of device…"

According to the proposed indications for use from your K162706 submission, the subject device is "indicated for type communication through a powered device, and is specifically designed to assist those with Carpal Tunnel Syndrome (CTS) to perform all of the tasks associated with typed communication…" According to the device description provided in your submission, the subject device is similar to the general QWERTY keyboard in shape and dimensions, but has an alternative keyboard configuration.7 In this case, I have determined that [Carpal Tunnel Syndrome] CTS is a form of "physical impairment" and that use of your device to "assist those with [Carpal Tunnel Syndrome] CTS to perform all of the tasks associated with typed communication" constitutes a "medical purpose." Therefore, your subject device can be considered as an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information and is used by persons unable to use normal communication methods because of physical impairment. Despite differences in layout between your subject device and a conventional keyboard, I have determined that the subject device still utilizes the same fundamental technology as a specialized typewriter or other powered communication system under 21 CFR 890.3710.

Because the subject device is not intended for a use different from the intended use of a legally marketed device in that generic type of device, and because it does not operate using a different fundamental scientific technology than a legally marketed device in that generic type of device, it does not exceed the limitations of exemption set forth in 21 CFR 890.9. Therefore, a premarket notification is not required to market the Finger Relief for an intended use that is consistent with 21 CFR 890.3710.

3) The labeling for the Finger Relief must not be false or misleading.

Please be advised that the determination that the Finger Relief is a Class II, 510(k)-exempt device when marketed for an intended use that is consistent with 21 CFR 890.3710 does not mean that the Agency has concluded that all the statements in your draft labeling or in your 510(k) are truthful and accurate. A device is considered misbranded "if its labeling is false or misleading in any particular."8 Therefore, it is your responsibility to comply with the FD&C Act to prevent misbranding of your device by ensuring that any statements in your labeling are supported with evidence so as not to be false or misleading.

Although premarket review of the evidence used to support your labeling is not required for a Class II, 510(k)-exempt device, this evidence should be kept on file at your Company's facility and may be reviewed during an FDA inspection.

Conclusion

Finger Relief is a class II, 510(k)-exempt device under 21 CFR 890.3710 (Powered communication system) when intended for use by persons unable to use normal communication methods because of physical impairment, which includes CTS. Therefore, a premarket

[Facsimile edited for length and relevancy. © Proprietary Disclosure by privacy release only.]
notification is not required to market the Finger Relief for an intended use that is consistent with 21 CFR 890.3710.

This determination is based solely on the information in the administrative record and appeal, including, without limitation, the description of the device, the intended use, proposed labeling and promotional material. Please be advised that if there is a change to the device, such as a change in fundamental scientific technology or a change in intended use (e.g., as reflected by labeling or promotional materials), such change may result in the product exceeding the limitations to the exemption in 21 CFR 890.9, and a premarket submission may be required. Please also be advised that this determination does not mean that the FDA has determined that your product complies with other requirements of the Act and FDA regulations or any Federal statutes and regulations administered by other Federal agencies.

This decision reflects the findings of my supervisory review of your appeal at the Office level. ***
Sincerely,
/s/
Jonathan P. Jarow, M.D. 2019.06.17 10:46:34 - 04'00'
Assistant Director, Clinical and Scientific Policy Staff
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

1 K162706/S002, 510(k) Summary, at 1.
2 K162706/S002, 510(k) Summary, at 1 – 2.
3 K162706/S002, Labeling, at 1 – 11.
4 Section 513(i)(1)(A) of the FD&C Act.
5 Sections 513(i)(1)(A)(i)-(ii) of the FD&C Act.
6 On November 3, 1998, FDA published a final rule in the Federal Register (63 FR 59231) exempting powered communication systems from premarket notification. It should be noted that this exemption occurred after clearance of the K930044 predicate on July 14, 1994.
7 K162706/S002, 510(k) Summary, at 1.
8 Section 502(a)(1) of the FD&C Act (21 U.S.C. § 352(a)(1)).