Introducing the first and only medical device authorized by the FDA to help reduce the symptoms of Fibromyalgia*

Now there's a non-medication option to offer your patients that could get them more active and feeling better. True wearable technology designed to meet the needs of your Fibromyalgia patients.

- Can be worn throughout the day and even during sleep
- Device is only 7mm thick so it can be comfortably worn under clothing
- A built-in accelerometer automatically regulates stimulation to optimize treatment during activity and sleep so the patient can "**wear it and forget it**"

- Mobile app provides real-time feedback and customizable settings like automatic **time of day adjustments** and **weather alerts**
- Rechargeable battery provides 3-4 days of treatment on a single charge
- Can consistently deliver high output power (120 volts, 100 milliamps) to cover all body types
- **Covered by 24 US patents**

Quell Fibromyalgia is available via our Pathfinder Strategic Launch Program. To learn more contact us via email at info@quellfibromyalgia.com.

Quell
Fibromyalgia
www.QuellFibromyalgia.com

*Quell Fibromyalgia is indicated as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity. The device may be used during sleep. The device is contraindicated for use by patients who have a cardiac pacemaker, implanted defibrillator, other implanted electronic device, or implanted metal near the device.

Quell Fibromyalgia was studied in a double-blind, randomized, sham-controlled trial[1]

- 119 subjects with physician diagnosed fibromyalgia who also met the American College of Rheumatology 2010 diagnostic criteria.
- Subjects randomized to active or sham treatment for 3-months.
- Analyses conducted on the intention-to-treat population (ITT, N=119) and a prespecified high pain sensitivity subgroup (N=60). The trial did not meet its primary endpoint of a significant mean difference in the 3-month PGIC[2] scores between the active and sham treatment arms for the ITT population. However, this difference was significant in the high pain sensitivity subgroup. This is the patient population for which the FDA granted De Novo authorization.

Key Study Results (in high pain sensitivity subgroup)

58% vs 30%

58% of subjects in the active arm compared to 30% in the sham arm (p=0.025) reported at least moderately better symptoms and overall quality of life.[2]

58% vs 28%

58% of subjects in the active arm compared to 28% in the sham arm (p=0.019) reported a clinically meaningful reduction (≥15%) in fibromyalgia impact.[3]

60% vs 18%

60% of subjects in the active arm compared to 18% in the sham arm (p<0.001) reported at least a moderate reduction (≥30%) in pain intensity.[4]

Note: The percentage of patients expected to obtain meaningful symptom improvement in routine clinical practice has not yet been determined.

[1] Source: Clinical Study Report "Efficacy of the Quell Wearable Device for Fibromyalgia" submitted in De Novo request DEN210046.

[2] PGIC, patient global impression of change. Subject responds to the question "Since beginning treatment at this clinic, how would you describe the change (if any) in activity limitations, symptoms, emotions and overall quality of life, related to your painful condition?" using a 7-point categorical scale that ranges from (1) "no change or condition has gotten worse" to (7) "a great deal better and a considerable improvement that has made all the difference."

[3] Fibromyalgia Impact Questionnaire (FIQR) total score.

[4] Fibromyalgia Impact Questionnaire (FIQR) pain item. The assessment of pain intensity was not anatomically specific and therefore it was not possible to determine the locations of pain relief. The current understanding of transcutaneous electrical nerve stimulation is that pain relief occurs in the dermatomal distribution of the stimulated nerves. Therefore, the primary area of pain relief should be assumed to be the ipsilateral lower extremity.

Quell Fibromyalgia

www.QuellFibromyalgia.com