

Nemaura Medical Inc

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Nemaura Medical rounds out successful human factors usability study for sugarBEAT glucose monitor

Nemaura Medical Inc (NASDAQ:NMRD) announced Tuesday that it has successfully completed two summative human factors usability studies for sugarBEAT, the world's first painless non-invasive glucose monitor.

It is crucial for medtech companies to demonstrate that they have taken human factors into account while engineering their advanced medical devices.

Nemaura's usability studies were conducted in line with the US Food and Drug Administration's guidelines on "Applying Human Factors and Engineering to Medical Devices." It brings the Loughborough, England-based medical technology company a step closer to submitting its medical device application to the FDA for SugarBEAT.

READ: Nemaura on track for FDA's De Novo submission for sugarBEAT glucose monitor in 2Q

The two studies consisted of 16 participants each, including both Type I and Type II diabetics. Participants in the first and second study ranged from ages 18-50 and 51-70 respectively. The studies were designed to ensure adequate information was captured for the diverse age groups expected to use SugarBEAT. The objective of the two studies was to confirm that the user interface aspects of SugarBEAT met the FDA guidelines for medical devices.

"We are pleased to have successfully completed these important studies and we are preparing our FDA filing at this time," said Nemaura Medical CEO Faz Chowdhury.

Chowdhury told investors that the company plans to apply to the FDA in the second quarter of 2019, which could speed up sugarBEAT's arrival on American shores.

For certain low-risk novel devices, the FDA's De Novo pathway offers a swifter route to market.

The FDA created the De Novo process in 1997 as an alternative pathway for companies bringing novel Class I and Class II devices to market via the pathway. The goal is to bring more transparency and predictability for manufacturers.

SugarBEAT is targeted at people with Type I and Type II diabetes, as well as for screening prediabetic patients.

Market disruptor

Since sugarBEAT doesn't require needles or insertion, it is likely to disrupt the continuous glucose monitor (CGM) device market. It will challenge entrenched players like DexCom Inc (NASDAQ:DXCM), which markets the Dexcom G6 and Abbott Laboratories' (NYSE:ABT) Libre System.

SugarBEAT consists of a daily disposable adhesive skin-patch connected to a rechargeable transmitter, with an app

Price: 0.75

Market Cap: \$156.01 m

1 Year Share Price Graph



October 2018 April 2019 October 2019

Share Information

Code: NMRD

Listing: NASDAQ

52 week	High	Low
	2.25	0.67

Sector: Medical technology & services

Website: www.nemauramedical.com

Company Synopsis:

Nemaura Medical Inc. is a medical technology company which has developed sugarBEAT® as a non-invasive, affordable and flexible continuous glucose monitor (CGM) designed to improve glucose management for all people with diabetes and pre-diabetics.

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displaying glucose readings at five-minute intervals for periods up to 24 hours. The innovation of sugarBEAT lies in its groundbreaking skin-patch technology, which allows for better glucose management.

"We anticipate broader adoption of SugarBEAT as compared with competitive offerings given SugarBEAT is non-invasive with flexible wear time, and will be attractively priced," said Chowdhury.

Chowdhury, a serial inventor and entrepreneur, is the brains behind sugarBEAT. The pharmaceutical scientist received his PhD in Nanomedicine from the University of Oxford. Today, Chowdhury holds 50 patents on drug delivery systems and sensors, across 15 technology platforms.

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