BBS-Bioactive Bone Substitutes - Insider information: BBS updates estimate of the CE marking approval schedule of ARTEBONE® Paste

BBS-Bioactive Bone Substitutes, Company announcement, Insider information, 30 December 2022 at 2:00 p.m.

In March 2022, BBS-Bioactive Bone Substitutes Plc ("BBS") submitted a CE marking application to the Notified Body related to the company's first product (ARTEBONE® Paste bone filler). At the time, the authorities estimated that the approval process would take 8-12 months from the application submission date (9 March 2022).

The CE marking process includes two main streams: approval of the quality system and product approval.

The first audit related to the approval of the quality system was successfully completed with the Notified Body between 15-18 November 2022. No critical non-conformities related to the quality system were reported during the audit. The second audit related to the quality system is tentatively scheduled for February 2023.

As part of the product approval process, the Notified body continues to review the documentation provided by the company. It has submitted the first questions and supplemental requests to the company. Requests did not contain any observations of significant deficiencies. Obtaining the CE marking requires not only the granting of the product approval, but also the approval of the aforementioned quality system.

"Getting the product approval requires cooperation between the Notified body and the Medicines Agency. According to the latest information we have received, the Notified body has not yet started the process with the Medicines Agency. Also, based on the publicly available statistics* related to CE marking applications, the average application processing times have increased in 2022," says Ilkka Kangasniemi, CEO of BBS.

For the above-mentioned reasons, the company currently considers it unlikely that the company will receive the final CE marking approval by the end of March 2023, based on the information which is currently available.

"Although we now consider a delay is likely due to the processing times of the authorities, the company itself still continues to advance the application process according to the previously communicated schedule estimate. Overall, we are satisfied with the progress of the application process in terms of substance and therefore remain confident about receiving the approval. Still, we cannot influence the processing schedule of the authorities", says Kangasniemi.

" Based on the information received from the authorities, it is currently very difficult to assess the authorities' schedules. The new MDR regulation has congested the application processing activities of the authorities, because in addition to new products, all products already on the market have to be re-registered as well. Despite the authorities' expected delays, we believe that receiving the approval will be possible during 2023. The company will publish more information about the schedule when additional information about the CE marking process is available."

* MedTech Europe Survey: https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf

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BBS in brief

BBS-Bioactive Bone Substitutes is a health technology company that started operations in 2003. We have developed a new product for the treatment of severe bone fractures and lumber problems. Our goal is to provide a new generation of medical products for the treatment of bone damage in orthopaedic surgery. In the pharmaceutical sector, development and research requires perseverance and courage to develop new things. We have evidence of this for over 20 years. Our activities are characterised by top expertise, innovation and employees who are enthusiastic and committed to their work. The ARTEBONE ® in the final stages of product development, and we are looking for a CE marking that enables commercialisation in the EU. We are a company in Oulu with a pharmaceutical factory permit in Reisjärvi.

BBS-Bioactive Bone Substitutes Oyj:n shares are listed in Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden.
More information: www.bbs-artebone.fi