

# BBS-Bioactive Bone Substitutes Plc – Insider information: The company updates the status of the CE marking process

BBS-Bioactive Bone Substitutes Plc | Company Release | November 05, 2024 at 19:00:00 EET

## Insider information: The company updates the status of the CE marking process

BBS Bioactive Bone Substitutes Oyj 's Notified body BSI has become to the conclusion that the provided clinical data is insufficient as required by the new MDR and as a result they will proceed refusal to review the ARTEBONE® application for certification. Notified body has promised to deliver the official refusal document within 2 weeks.

Once the deficiencies have been corrected, the company can submit a new CE marking application according to Notified body. The company wants to emphasise that, during the meeting, no remarks were made regarding the ARTEBONE® implant itself.

At this stage, the company will not provide further information about future plans but will issue additional details in a separate announcement later.

## The product's journey towards commercialization (updated)

Phase	Action	Status
Product development	Preclinical animal tests	Completed
	Functionality and efficiency tests	Completed
	Clinical test	Completed
CE marking	Submitting the CE application	Completed
	Quality system application	Approved
	1st audit	Completed
	2nd audit	Completed
	Additional audit	Completed
	Additional measures	Completed
	Product approval	Suspended
	Product classification	Completed
	Consultation with the Medicines Agency	Suspended
	Production lines and line certification	In process
Commercialization	Preliminary commercialization	In process
	Extensive commercialization	In preparation

### **Previously published announcements related to the CE marking application**

- May 5, 2024 – Insider information: The company updates the status of the CE marking process – CE-mark process will not be completed by the end of the second quarter in 2024
- November 25, 2023 – The Notified Body has approved the Company's quality system
- November 2, 2023 – Insider information: The company provides an update on the CE marking process related to the approval of the quality system – consultation with the Finnish Medicines Agency to begin on 21 November 2023
- September 13, 2023 – Insider information: Plan to complete minor open issues approved – the Company updates its outlook on the schedule of the CE marking
- August 31, 2023 – Inside information: The final report of the additional audit received from the Notified Body
- May 26, 2023 – Inside information – Positive decision received on the product classification, schedule for the quality system approval to be updated
- March 27, 2023 – Inside information: The final report of the second audit received from the Notified Body, the CE marking process may continue and CE marking approval continues to be expected during 2023
- December 30, 2022 – Insider information: BBS updates the estimate of the CE marking approval schedule of ARTEBONE® Paste
- November 18, 2022 – Inside information: The first audit completed by the Notified Body, CE marking process may continue as planned
- March 9, 2022 – BBS Bioactive Bone Substitutes Plc has filed the CE-marking application of Artebone® bone void filler to the authorities

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**BBS in brief**

*BBS -Bioactive Bone Substitutes Plc is an orthobiology company that started its operations in 2003. We have developed a new product for the treatment of complex bone fractures and bone healing issues. Our goal is to provide next-generation medical products for the treatment of bone injuries in orthopedic surgery. In the pharmaceutical industry, the development and research work require perseverance and courage to innovate. We have a track record of over 20 years in this field. Our company is characterized by expertise, innovation, and dedicated employees who are passionate about their work. Our first developed product, ARTEBONE® Paste, is in the final stages of the CE marking process to enable its commercialization in the EU market. We are based in Oulu with a medical manufacturing facility in Reisjärvi, holding a manufacturing license. The company's headquarters are in Oulu, and we employ over 20 people.*

*BBS has been listed on Nasdaq First North Growth Market Finland since February 2018.*

*More information: [www.bbs-artebone.fi](http://www.bbs-artebone.fi)*