Press release
Uppsala, November 16, 2020

Doxa receives FDA 510(k) clearance of Ceramir® Restore QuikCap

Doxa's 510(k) submission for Ceramir® Restore QuikCap has been cleared by the U.S. Food and Drug Administration (FDA). This entails that Ceramir Restore QuikCap now can be marketed and sold in the United States. The market launch has been planned during the fall, and the first produced batch is projected to be delivered to distributors before the end of 2020.

"*Ceramir Restore represents a major advance towards becoming a company with a portfolio of products based on our unique Ceramir technology. The 510(k) clearance is one result of the development work that has involved the entire company, and I am proud to lead the team behind this accomplishment. It is gratifying that we have been able to focus our resources on completing this project, which has been underway for a long time. We are now awaiting the 510(k) clearance of our other novel product, Ceramir Protect,"* Says Henrik Nedoh, CEO of Doxa.

Ceramir Restore is a bioactive dental filling material based on Doxa's unique Ceramir technology. The product is particularly well suited for dental care of children and seniors, as the technology's properties achieve the best results in these applications. The product falls within the category of dental filling materials for small-to-medium-sized fillings that are subject to a moderate amount of pressure. The initial feedback from users who have tested the material in simulated clinical testing has been very positive. Several of our Key Opinion Leaders are now looking forward to carrying out clinical testing of the material to be able to evaluate its uniqueness and the advantages it offers over competing materials. Just like Ceramir C&B, Ceramir Restore has the ability to remineralize the tooth tissue by means of a high pH level and calcium release, which creates dense and durable connections between the tooth tissue and the material. The market segment that Ceramir Restore now targets is estimated to be worth approximately MUSD 40 annually.

As the possibilities to conduct traditional marketing and sales work have been limited during the pandemic, Doxa made an early decision to focus the company's resources on product development during 2020. The now obtained 510(k) clearance is the result of this determined effort and constitutes a milestone for the development of Ceramir Restore as well as for Doxa as a company. The company's product portfolio thus expands to four products.

The 510(k) clearance allows the company to finalize the preparations to make the product available to U.S. distributors. The plan is for distributors to be able to offer and supply the product at the turn of the year; the precise timing may vary depending on the product introduction processes of each respective distributor.

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The Ceramir product: www.ceramir.se

This information is information that Doxa Aktiebolag (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the CEO, at 20:20 CET on November 16, 2020.

DOXA IN BRIEF

Doxa is a dental company based in Uppsala, Sweden, which develops, manufactures and commercializes bioactive, tissue-friendly and easy-to-use products for global dentistry. The basis of development is a well patented bioceramic technology. Our products, which currently are sold and marketed under the product names Ceramir®, Ceramir Crown & Bridge and Ceramir Bioceramic Implant Cement, are remineralizing, tissue-friendly and (for the dentist) time-efficient dental cements for permanent cementation of crowns and bridges. Doxa Aktiebolag (publ) is listed on Nasdaq First North Growth Market with Redeye AB as the company's Certified Adviser (telephone: +468-121 576 90; e-mail: certifiedadviser@redeye.se).

This document is a translation from Swedish of a previously published press release.
In case of divergence between the language versions, the Swedish version shall prevail.