OssDsign receives expanded FDA market clearance for OssDsign Cranial PSI

Uppsala, October 4, 2021 – OssDsign today announced that it has received expanded market clearance from the US Food and Drug Administration (FDA) for OssDsign Cranial PSI – a patient-specific cranial implant. The clearance highlights the osteoconductive properties of OssDsign's patented calcium phosphate composition to be resorbed and replaced with bone tissue.

The new 510(k) clearance builds on an initial market clearance in 2017 and means the FDA has now cleared that the osteoconductive ceramic component of OssDsign Cranial PSI is resorbed and replaced with bone tissue during the healing process.

"We are delighted that the FDA recognizes the osteoconductive properties of OssDsign Cranial PSI. This is an acknowledgement of the product's ability to be replaced with bone during the healing process, and there is a growing body of scientific evidence that links active bone metabolism to lower complications rates," says Morten Henneveld", CEO, OssDsign.

OssDsign's titanium-reinforced calcium phosphate implant is designed for the reconstruction of cranial defects, an area of treatment where post-operative infections are considered one of the most common complications. Both published data and clinical documentation show that OssDsign Cranial PSI is associated with a low risk of infections in the early postoperative stage, which may otherwise lead to the need for implant removal.

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About OssDsign
OssDsign's vision is to provide regenerative solutions to all patients with cranial or spinal bone defects, so they can b e restored and healed as naturally as possible. Driven by a commitment to give patients back the lives they deserve, OssDsign collaborates with surgeons to engineer better healing by integrating biomaterials with clinical design. Headquartered in Sweden, OssDsign supplies hospitals worldwide with implants for use in cranial reconstructions and other orthopaedic surgery applications.

This information is information that OssDsign AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact person set out above, at 08.00 CET on October 4, 2021.