

20 March 2025

Company Announcements Office
Australian Securities Exchange

Nanosonics Receives FDA De Novo Clearance for CORIS® Innovation

Nanosonics Limited (ASX: NAN), a leader in infection prevention solutions, announces the U.S. Food and Drug Administration (FDA) has granted De Novo clearance for its innovative CORIS® system.

CORIS is a novel technology designed to reduce infection risk and enhance patient safety by delivering improved cleaning outcomes for flexible endoscopes, in particular, the complex channels of endoscopes which are prone to biofilm build up. Through an automated mechanism of action, CORIS combines cutting-edge science and engineering with practical usability to address what is recognised as one of the most critical challenges in medical device reprocessing today.

“CORIS represents a significant opportunity for the organisation and the FDA de novo clearance marks a key milestone for the Company and an important step in bringing this much needed innovation to market”, said Michael Kavanagh, CEO and President.

“The CORIS system has been designed to automate and provide superior cleaning outcomes for the channels of all categories of flexible endoscopes. The initial submission to the FDA was associated with colonoscopes and the intent is to expand these indications to cover all major categories of flexible endoscopes over time.

“The Company continues its preparations for commercial launch including obtaining the necessary approvals in the UK, Europe and Australia. These approvals are expected to be in place during Q1 of FY26. In parallel, the first 510K submission for expanded scope indications is being prepared for FDA submission.

The first phase of commercialisation remains on track for the first quarter of fiscal 2026 (Q1 FY26)¹. This phase will focus on raising market awareness and conducting a targeted controlled market release with a number of hospitals to gain initial experience before a broader roll out. After this initial phase, we plan to introduce the product more broadly in the initial launch countries. Based on the results from the first phase, we expect to commence broader market introduction in the second half of fiscal 2026 (H2 FY26)”.

Michael Kavanagh
CEO / President

Authorised by the Board of Directors of Nanosonics Limited.

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¹ All research and new product development programs involve inherent risks and uncertainties which can impact commercialisation timelines.