Press Release
13 November 2026 12:45:00 CET

Paxman Announces FDA Advancement of Its Neuropathy Device De Novo Application to Substantive Review

Paxman announces today that the U.S. Food and Drug Administration (FDA) has successfully completed the acceptance review of the Company's De Novo submission for the Paxman Neuropathy following a request for supplementary material and has now advanced the application into the substantive review phase.

Completion of the acceptance review confirms that the FDA has determined the submission is sufficiently complete for comprehensive scientific and regulatory evaluation.

Under the De Novo pathway, which applies to novel medical devices without a legally marketed predicate, the substantive review involves a detailed assessment of Paxman's clinical, technical and supporting evidence.

The FDA's target review timeline for a De Novo submission is 150 review days. The official start date from submission was 26th October 2026, leaving 134 days remaining. However, the process includes opportunities for the Agency to request additional information or clarification. Such requests temporarily pause the review clock while responses are prepared and submitted by Paxman.

Richard Paxman, CEO, commented: "Advancing to substantive review marks another important milestone in the regulatory pathway to bring the Paxman Neuropathy device to patients who may benefit from protection against chemotherapy-induced peripheral neuropathy, a side effect that can have a lasting impact on quality of life. We are pleased that the FDA has completed its acceptance assessment and has now begun a detailed review of our submission. Requests for additional information are a normal part of the De Novo process, and our team is well prepared to provide timely and comprehensive responses to any questions. While regulatory review timelines can vary, De Novo submissions can typically take approximately six to twelve months to complete. Further updates on material developments will be provided as they occur."

Chemotherapy-induced peripheral neuropathy (CIPN) is a severe dose-limiting toxicity of paclitaxel and docetaxel, which are both widely used drugs for the treatment of common cancers including breast, ovarian, endometrial, lung, and gastric cancers. CIPN is an unseen, debilitating, and lifelong condition that severely impacts the quality of life of cancer patients. Prevention of nerve damage is currently a major unmet clinical need; the Paxman Neuropathy device is a breakthrough innovation helping to reduce the risk of peripheral neuropathy progression while supporting patients to remain on their prescribed treatment.

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About Us

Paxman Group is a global medical technology company focused on improving quality of life for people undergoing chemotherapy through innovative side-effect management solutions. Its portfolio addresses two of the most challenging treatment-related side effects: chemotherapy-induced alopecia (hair loss) and chemotherapy-induced peripheral neuropathy (CIPN).

Paxman Group's scalp cooling technologies, including the Paxman Scalp Cooling System and the DigniCap Scalp Cooling System, are used globally in hospitals and cancer centres to support patients undergoing chemotherapy by helping to reduce the risk of chemotherapy-induced hair loss. The clinically validated Paxman Neuropathy System supports the prevention of CIPN through cryocompression technology.

Founded through the Paxman family's personal experience of cancer treatment, Paxman Group works with patients, clinicians and research partners to advance side effect management in cancer care globally.

PAXMAN AB (publ) has its headquarters in Karlshamn (Sweden). Subsidiaries of the PAXMAN Group are Paxman Coolers Limited (Huddersfield UK), Paxman Inc. (Houston, Texas US), Paxman Canada (Toronto, Ontario CA), Dignitana AB (Lund, Sweden), Dignitana Inc. (Dallas, TX US), and Dignitana S.r.l. (Milan, IT).

Paxman AB (publ) is listed on Nasdaq First North Growth Market with FNCA Sweden AB as Certified Adviser.

Attachments

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