PAXMAN
PIONEERS IN SCALP COOLING

PAXMAN announces 510k Submission to the U.S. Food and Drug Administration (FDA) for the Paxman Cryocompression Device to Prevent Chemotherapy-Induced Peripheral Neuropathy (CIPN)

Paxman announces today that the U.S. Food and Drug Administration (FDA) has confirmed receipt of the 510k Submission for the Paxman cryocompression device to prevent chemotherapy-induced peripheral neuropathy (CIPN).

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective. This follows the news in October, that the Paxman device, was accepted into the US FDA's Safer Technologies Program (STeP), and additionally, confirmation that the Category III CPT® Code Application for the device, submitted to the American Medical Association (AMA) in November, is to be included on the Proposed Agenda for the February 2026 CPT® Editorial Panel Meeting.

These steps mark significant milestones in Paxman's regulatory pathways towards FDA clearance of this new technology. Product launches in select markets are currently being planned for 2026 with launch to all markets anticipated in 2027. More information regarding timelines will be communicated in the New Year.

Richard Paxman, CEO, commented, "This news mark further critical steps forward in our commercialisation process for the Paxman Cryocompression Device, and most importantly, advances our efforts to address the substantial unmet clinical need of reducing CIPN incidence and severity in patients undergoing taxane-based chemotherapy."

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.

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About Us

The Paxman Scalp Cooling System has been developed by the Paxman family to reduce hair loss in breast cancer patients undergoing chemotherapy. The concept behind the system came when the mother of four, Sue Paxman, experienced first-hand the trauma of chemotherapy-induced hair loss. In 2025, PAXMAN AB acquired Dignitana, merging to form a stronger united company.
Today, PAXMAN's portfolio includes both the Paxman and DigniCap systems with several thousand installations in hospitals, clinics and treatment centres worldwide, reaffirming PAXMAN as the leading global supplier of Scalp Cooling technology.
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).

The PAXMAN share is listed on Nasdaq First North Growth Market.
FNCA Sweden AB is the company's Certified Adviser.

Attachments

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