

# BrainCool AB (publ) Receives US FDA De Novo Clearance for the Cooral® System for Reduction of Oral Mucositis

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ANNAPOLIS, MARYLAND, UNITED STATES, November 1, 2022 /EINPresswire.com/ -- BrainCool Inc a subsidiary of the Swedish medical device innovator BrainCool AB (publ), announced the launch of Cooral® System which has been approved through a De Novo clearance by the U.S. Food and Drug Administration (FDA).

The market clearance paves the way for reduction of one of the most severe side-effects of chemotherapy, Oral Mucositis (OM). OM is a severely debilitating condition characterized by erythema and ulcerations of the oral mucosa ([National Cancer Institute](#)).

The Cooral® System, which also has a Breakthrough device approved by the FDA, a designation implemented by the FDA in 2018 intended to increase delivery of innovative medical devices that "provide for more effective treatment or diagnosis of life-threatening, or irreversibly debilitating diseases."

"This is a significant milestone for the Cooral® System," said Martin Waleij CEO BrainCool AB (publ). "We are proud of being one of the first cleared products with a 'Breakthrough' Designation" and now look forward to bringing the device into clinical practice where it can actively benefit US patients without further delay."

The Cooral® System, has shown statistically significant evidence related to safety and effectiveness in clinical trials. A Scandinavian clinical study presented at a late breaking session during the 2020 [European Society for Medical Oncology's Virtual Meeting](#) was published in [Bone marrow transplantation](#).

Troy Van der Veur - "We are thrilled with the FDA approval of the Cooral® System. BrainCool Inc. remains committed to enhancing temperature management therapies and empowering clinicians to elevate the standard of care. Our IQool System continues to be adopted at hospitals across the US due to clinical and financial differentiators and we're excited to add the Cooral® System to our portfolio as it will clearly benefit oncology patients undergoing chemotherapy."

The Cooral® System offers a solution to improve the quality of life for patients undergoing chemotherapy by providing medical professionals a proven method to prevent OM.

The Cooral® System includes a device that circulates cold, sterile water through a mouthpiece fitted to the patient. Cryotherapy (cold therapy) is administered and reduces blood flow to a targeted area. Consequently, metabolism is slowed which reduces the risk of developing OM.

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#### About Oral Mucositis (OM)

OM is a highly significant and sometimes dose-limiting condition that has been reported as the single most-debilitating complication of cancer therapy. OM can be present in combination with a variety of debilitating symptoms that may compromise the ability of patients to maintain oral hygiene practices. For example, intractable oral pain, which may lead to an increased need for analgesics and, on occasions, opioids that are administered intravenously. OM is further associated with undernourishment, weight loss, the use of feeding tubes or total parenteral nutrition, and impaired quality of life, and it can represent a portal of entry for systemic infections that can lead to sepsis and death. Taken together, these symptoms, along with their related sequelae, can result in extended hospitalization with increased costs for healthcare systems.

#### Files for Download:

Study: <https://doi.org/10.1038/s41409-021-01512-6>

For more information about Cooral: [www.coolprevent.com](http://www.coolprevent.com) and [www.braincoolinc.com](http://www.braincoolinc.com)

#### About BrainCool AB (publ)

Based in Lund, Sweden, Europe, BrainCool AB (publ) (Spotlight markets BRAIN) is a publicly traded medical device company focused on next-generation temperature management systems. The company has two business units, braincooling, with the two CE marked products BrainCool System and RhinoChill, and in oncology with the Cooral® System. BrainCool, Inc, the U.S. subsidiary of BrainCool AB, is based in Annapolis Maryland. The IQool® System, which received FDA 510(k) Clearance in 2019, was the first BrainCool product to be marketed in the United States. Braincool Inc, will now also market the Cooral® System.

#### About CoolPrevent AB

CoolPrevent AB is a fully owned subsidiary of BrainCool AB (publ), an innovative medical device company that develops, markets, and sells leading medical cooling systems. These systems offer significant medical benefits to cancer patients, empowering them during their journey

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