Press Release
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BrainCool AB (publ): BrainCool Receives FDA 510 (k) Clearance for Updated IQool™ System

Today we announce that the updated IQool™ System has received a new 510 (k), clearance from the U. S. Food and Drug Administration (FDA), through the special 510 (k) program, ref (1).

This clearance covers updated software and electronics for improved temperature regulation primarily for the neurological fever segment. The changes are already implemented in production of the 100 units of IQool™ System that is the planned production until end of Q1 2024.

The BrainCool™ System (branded IQool™ System in the United States) is an advanced surface temperature management system with gel-free and adhesive-free pads that maintains fever control and manages patient temperature in critical care settings. The IQool™ System features an intuitive user interface, programmable protocol settings and acute temperature control.

CEO Martin Waleij comments
-" The 510 (k) clearance of the updated IQool™ System, will further strengthen our position in the market and is consistent with our commitment to quality. We are pleased as well with the fact that we submitted this 510 (k) September 13th, 2023, and turned around the clearance within one month."

Reference
1. The Special 510(k) Program | FDA

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About Us
BrainCool AB (publ) is an innovative medical device company that develops, markets, and sells leading medical cooling systems for indications and areas with significant medical benefits within the healthcare sector. BrainCool AB (publ) is based in Lund, Sweden, and its share is listed on Nasdaq First North Growth Market, named "BRAIN".
Eminova Fondkommission AB is the company's Certified Adviser.

Attachments
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