

BrainCool receives market approval for BrainCool™ System in Malaysia

BrainCool AB (publ) announces today that it has received market approval for BrainCool™ System in Malaysia. BrainCool's distributor, ZOLL®, can now start commercializing the system in the Malaysian market. BrainCool™ System offers precision temperature management of the body, for example, to improve survival and reduce permanent disability in people suffering from sudden cardiac arrest or stroke.

BrainCool's partner for the commercialization of BrainCool™ System, the global medtech company ZOLL®, is one of the leading players in medical precision cooling. ZOLL® has a dedicated sales force for BrainCool™ System in the US and the DACH region (Germany, Austria and Switzerland). According to an extended distribution agreement, ZOLL® will market and sell BrainCool™ System in five ASEAN countries – Thailand, Malaysia, Singapore, Indonesia and the Philippines – as well as Taiwan and Pakistan. BrainCool will start delivering the systems after market approval in each of these countries.

"Last year, we obtained market approval for BrainCool™ System in Thailand as the first country in our extended agreement with ZOLL®. With the recent approval in Malaysia, we can now leverage these two approvals to achieve market approval in other countries covered in our agreement with ZOLL®," said Jon Berg, CEO of BrainCool.

The regulations for the ASEAN countries are harmonized under common directives for medical products as outlined in the ASEAN Medical Device Directive (AMDD). Each country is at a different stage in the harmonization process. BrainCool has initiated the application processes for approval in further countries, as the approvals in Thailand and Malaysia can facilitate the processes in the other ASEAN nations according to the AMDD directives.

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For more information

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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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