

Magle Chemoswed submits updated regulatory file to European Notified Body

Magle Chemoswed has submitted an updated regulatory file for approval of its first in class SmartPan bio-indicator product for use in pancreatis surgeries.

Magle Chemoswed announces that the Company submitted a final medical device Technical File application to the appointed European Notified Body for CE mark approval of its SmartPan product.

SmartPan, a first in class patented product, developed with surgeons at the University of Heidelberg is based on Magle Chemoswed's bio-compatible and bio-degradable microsphere technology. SmartPan is a sterile medical device that detects pancreatic leakage immediately on contact with pancreatic fluid at the surgical closing site and contains a unique combination of microspheres bound with an enzymatic indicator to detect pancreatic fluid. Leakage of pancreatic fluid from the pancreas after surgery is a common problem that can lead to serious post-surgical complications. SmartPan is an innovation that reduces the risk of pancreatic fluid leakage going undetected at the surgical point.

"I am extremely excited about SmartPan, not only is it a first in class product, but it also fills a very serious and pressing medical need. We have developed SmartPan in conjunction with world leading surgeons", says Justin Pierce CEO of Magle Chemoswed.

If the Notified Body clears the Company's application, SmartPan will be marketed in the European Union to start with and will be manufactured and supplied by Magle Chemoswed using the Company's in-house integrated manufacturing and packaging capabilities.

"The team's dedication in getting SmartPan to this stage is nothing short of sensational. This is another major milestone for Magle Chemoswed and is further strong evidence of the versatility of our technology platform and the strong depth of our pipeline," added Justin Pierce.

Contacts

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About Us

We are Magle Chemoswed, a Malmö-based contract development and manufacturing organization (CDMO) that serves companies in the pharmaceutical and medical device industry on a contract basis. We provide comprehensive services from product development through product manufacturing and we pride ourselves in coming up with solutions to complex healthcare challenges. Together with our customers, we take innovations from idea to product. Learn more on www.maglechemoswed.com.

Västra Hamnen Corporate Finance is the Company's certified advisor on Nasdaq First North Growth Market and can be reached at ca@vhcorp.se or +46 (0) 40 200 250.

Attachments

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