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Creo receives FDA Clearance for new Speedboat RS2 device and CROMA system

Aug 24 2017

Approval comes ahead of schedule; Company to implement commercial plans

Creo Medical Group plc (AIM: CREO), a medical device company focused on the emerging field of surgical endoscopy, today announces that it has received 510(k) clearance ("FDA Clearance") from the US Food and Drug Administration ("FDA") for its Speedboat RS2 device and the CROMA platform.

Speedboat RS2 is the first of a range of medical devices in development, powered by the CROMA platform, and enables the minimally invasive removal of early stage cancerous and pre-cancerous lesions in the bowel through an endoscopic procedure. This FDA Clearance has been received ahead of schedule, with the FDA review process being completed in 49 calendar days from submission. Accordingly, Creo will now assess the necessary steps to bring forward the implementation of its commercial plans for the US.

Speedboat RS2 is the first device developed for use with the Company's generator, CROMA. It harnesses the cut and coagulation capability of CROMA and enables the removal of early stage cancerous and pre-cancerous lesions. The use of Speedboat RS2 reduces the risks associated with incisions which are necessary for laparoscopic procedures and can reduce the length of hospital stay. Endoscopy has been a rapidly expanding practice due to the advent of colorectal cancer screening in most healthcare systems. This has driven growth in equipment and devices to enhance the ability to screen and detect early stage and pre-cancerous lesions in the GI tract.

In the US, over 16 million colonoscopies are performed annually. Of these, 1.1 million are likely to find a lesion requiring treatment, half of which are surgically removed. Traditional colorectal surgery is associated with a 6 per cent mortality rate at 30 days. Due to Speedboat RS2's ability to coagulate bleeding vessels when the microwave energy is activated by the surgeon, and to cut or resect when the RF energy is activated, the risk of puncturing tissue could be reduced, offering surgeons a minimally invasive alternative with an enhanced safety profile.

Craig Gulliford, Chief Executive Officer of Creo, commented:

> *"The FDA Clearance of Speedboat RS2 and the CROMA system, earlier than planned, is a critical step in our commercialization strategy. Speedboat is paving the way for our suite of GI devices, which we plan to commercialize in the EU, US and globally.*
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> *"This approval is a real testament to the hard work and dedication from the Creo team – we continue to execute against our plan and, in this case, come in well ahead of our targets. This bodes well and provides us with confidence that we have the foundations in place to execute on the suite of devices currently in development.*
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> *Over the coming weeks, we will be looking to bring forward the development of our US capabilities whilst continuing with the promising training program underway in Europe. Surgical endoscopy is an emerging field and we believe that with the CROMA system, Speedboat and our suite of products, we are well positioned to become a leader in this billion-dollar plus market.*

Source:

https://creomedical.com/