Spartan Micro Receives FDA 510k Clearance for its MC 0165 Microcatheter

Spartan Micro has received 510(k) Clearance from the U.S. Food and Drug Administration (FDA) for Spartan MC 0165 microcatheter.

Spartan Microcathater

COSTA MESA, CA, USA, November 29, 2021 /EINPresswire.com/ -- Spartan Micro has received 510(k) Clearance from the U.S. Food and Drug Administration (FDA) for Spartan MC 0165 microcatheter.

Spartan Micro, Inc. (Costa Mesa, CA), a developer of endovascular-based devices for use by interventional radiologists, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for Spartan MC 0165 microcatheter. The MC 0165 is offered in long lengths to reach the distal anatomy, the flexibility to get there and the support to deliver compatible therapeutic devices.

> This product has better reach, trackability, kink resistance and control than similarly positioned microcatheters in vitro testing."
>
> *Satoshi Tateshima, M.D., D.M.Sc.*

"This product has better reach, trackability, kink resistance and control than similarly positioned microcatheters in vitro testing," said Satoshi Tateshima, M.D., D.M.Sc, Spartan Micro's Chief Medical Advisor.

"We are pleased to add this to our growing portfolio of FDA cleared products," said Eric Stoppenhagen, CEO of Spartan Micro.

About Spartan Micro

Spartan Micro is a neuro and peripheral vascular medical device company based out of Costa Mesa, California. Spartan fills the stroke innovation gap abandoned by dominant medical device players. We develop products that resolve issues where current products are either not stable enough to maintain access, too big to get access, or otherwise cause damage during procedures. Our products are designed to optimize the delivery of the latest therapeutic devices, making it possible to go further and (safely) treat more distally. Pipeline products include over-the-wire, flow-guided microcatheters, guiding catheters, neurovascular stents and flow diversion stents.

Spartan Micro currently offers catheter access devices for neuro and peripheral vascular procedures. Additionally, we offer neuro and peripheral coils for the occlusion of aneurysms and or flow diversion of other vascular deformities.

Forward-looking Statements
This press release contains “forward-looking statements.” Such statements may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company’s control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction.

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