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Baltimore medical device startup joins TEDCO program

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A Baltimore medical device startup Tuesday became the latest company to join the Maryland Technology Development Corporation (TEDCO) mdPACE program.

Aimee Purcell Martin

The mdPACE program helps medical device startups navigate the federal regulatory approval process, with a particular focus on the Food and Drug Administration's 510(k) approval.

The program was founded under a grant from the U.S. Department of Commerce that awarded TEDCO $500,000, contingent on a one-to-one match.

The program is "about building innovation clusters," said Stephen Auvil, senior vice president at TEDCO. "The goal was to leverage all of this medical activity that we have and try to build a stronger cluster in this region."

BondTrue became the 18th Maryland startup to partner with the mdPACE program, which began three years ago.

The company's device automates the process of surgical incisions and closures, leading to a faster, more precise wound that can be quickly repaired.

BondTrue hopes it can take advantage of TEDCO's aid to more quickly navigate the regulatory process, Aimee Martin, the company's CEO, said in a statement.

"TEDCO brings a depth of medical device product development experience and commercialization acumen that will be critical to bringing BondTrue to market," she said. "We're eager to move through the stage-gate process with TEDCO's executive-level guidance so that we can accelerate the regulatory pathway for the BondTrue device, which has massive market potential for numerous types of surgeries including orthopedic and cardiothoracic procedures."

The mdPACE program brings in medical device executives with experience in the 510(k) regulatory process who can help companies preparing to seek approval. These executives have experience as engineers, doctors, FDA regulators and in product development.

Going through the program can help companies cut the application time from 36 months to between 18 and 24 months.

The program helps only companies going through the relatively easier 501(k) regulatory process because that process requires a predicate device – a similar device that has already received approval. A second process, the premarket approval, is a more difficult regulatory process that mdPACE companies do not participate in.

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The executives in the program help startups with things like finding the right predicate device, designing the device and deciding what it will do.

"(The program) is all very strategic in trying to get you through the approval process quickly," Auvil said.

Regulatory approval can be critically important for startups in the medical device field seeking investment.

Investors can be wary of devices that need approval because approval is a risk, Auvil said.

"We talk to these guys, and they say it's really hard to get investment because investors want to mitigate their risk. And FDA approval is a huge risk," he said. "Investors would prefer to wait until they get the FDA approval before they put their money in."

But gaining that approval can help the companies become more financially secure.

One company from mdPACE's program has received FDA approval. Three more could receive approval soon, Auvil said. Ten more companies could be filed, with eight receiving approval, over the next 10 months, he predicted.