MEDTECH INSIGHT
CITELINE COMMERCIAL

08 Sep 2023 | **Interviews**

Market Fast Track Or Regulatory Trap? Consultant Ken Block On US FDA's Breakthrough Devices Program

by Ryan Nelson

Ken Block of Ken Block Consulting weighs in on the FDA's Breakthrough Devices Program, its implications for raising capital, achieving speedier market access, and inviting more intensive regulatory scrutiny in this interview with *Medtech Insight*.

Speaking with *Medtech Insight* on 29 August, medtech industry consultant Ken Block said he'd just wrapped a call with a client and a US Food and Drug Administration representative regarding the former's novel medical device.

He explained, "It's a kind of a marketing-related call that FDA does" to say, "'We've identified your company as having a novel device.'"

According to Block, founder and president of Richardson, TX-based *Ken Block Consulting*, device manufacturers that have approached the agency with a pre-submission may be recipients of these calls, as well as those already in the Breakthrough Devices Program [BDP].

"Basically FDA sets up this call because FDA wants to make sure that they are attracting from around the world all those innovative devices that are either coming first to the US, or maybe in parallel with one other market. They don't want to be second, they don't want to be third," he said.

If a medical device company is targeting the US market first, the FDA wants to understand why and whether the BDP was a factor in its strategic considerations.

Key Takeaways

For Block's client, which already has a breakthrough device designation, the answer to that question was an emphatic yes. "We're confident we are going to get this on [the market], and we're going to get it on way earlier than we can for the European market, which is our second market. And this is a European company," Block said.

Block's firm has helped manufacturers attain breakthrough designations for a range of devices, including a software-controlled electromechanical device, a software-only device, and an orthopedic mechanical-only device. It also has begun work with an in vitro diagnostic company seeking breakthrough status.

- One of the Breakthrough Devices Program's biggest draws is the cachet it can have with investors.
- The program's modest marketing authorization rate to date could reflect heavy startup participation and the challenges implicit in being a breakthrough device.
- Breakthrough Device sponsors' experiences with the program may vary depending on review group and FDA enthusiasm for the project.

"So it really is across the board. It's not like, 'Gosh, if we just had software, if we just had AI.' You don't have to have AI to have a breakthrough," Block said.

KEN BLOCK, FOUNDER AND PRESIDENT, KEN

He noted one of the program's biggest draws: It can be a difference maker in the pursuit of funding.

"Let's say you're a company and you're looking for private investment and you think you've got something hot, it's going to burn up the market. But, you know, we're kind of running out of funds in six months. But, boy, if we could get breakthrough. We've got people chomping at the bit over here, saying, 'You show me progress with the regulator,' whatever that is. I mean, we're not ready for the market. So how do I show an achievement with a regulator?"

He continued, "I can get that [breakthrough] notch in my belt. Then the investors not only say, OK, you did something – but wait. You did something that could potentially prioritize the review of that eventual marketing submission?"

BLOCK CONSULTING

Not Fast Enough?

The BDP, launched in 2015, replaced the FDA's Expedited Access Pathway and Priority Review Program for medical devices. It has similar purposes, to facilitate timely patient access to medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions by expediting their development, assessment, and review.

There is some skepticism among stakeholders as to whether the program functions as advertised or popularly imagined.

Based on calculations performed using BDP data as of 30 June 2022, when 693 devices had been granted breakthrough designations and 54 had received marketing authorizations, Epstein Becker Green attorney Brad Thompson concluded last year that breakthrough devices took about a half-day longer to be 510(k)-cleared than comparable devices not in the breakthrough program.

For devices submitted through the de novo process, those with breakthrough status received a final decision 64 days faster than non-breakthrough devices on average, according to Thompson's *post* to Epstein Becker Green's "Health Law Advisor" blog.

The attorney acknowledged the limitations of his methodology and that "breakthrough devices by their very nature are more likely to be cutting-edge products technologically, and more likely to deal with serious diseases or conditions."

Still, "I would have to seriously question the value of the breakthrough device designation for devices that qualify for a 510(k). … On the other hand, for devices that need to go through the de novo process, I do think the data support the value of obtaining the breakthrough device designation," he said.

In Thompson's view, the FDA could be imposing a higher evidentiary standard on breakthrough products compared with those in traditional review pathways.

"If I were going to take the risk that FDA would tell me to develop much more expensive data than I had planned for a breakthrough device, I would want at least a more compelling case that the review time should be shorter for those that qualify," he said.

He went into more depth with *Medtech Insight* in a *September 2022 podcast*. Thompson stood by his analysis in a recent conversation.

Counterpoint

Block believes criticism of the BDP based on review time and approval rate comparisons may be misplaced and not account for key differences in the profiles of respective device sponsors.

In the BDP, he said, “instead of a 90-day review for 510(k), maybe they do it in 70. Is that a big whoop-de-do difference? No. But by definition of breakthrough, you're not ready for the market yet, you’re a device in development. If you've got everything figured out and you're ready to send in your submission, why do breakthrough? The breakthrough program is supposed to be something where you're collaboratively working with the FDA on a device that's in development.”

He provided the example of another Ken Block client that aims to submit a 510(k) using a de novo classification as predicate. “Is breakthrough going to be good for them? Yes. Because they would be the very first company coming after that de novo company. We don’t have another 510(k), we have to know what to compare ourselves against, and we don’t have that information yet because that’s not posted for a while. So we’re in the dark a little bit. We have to talk to FDA.”

One option for the company would be a pre-submission under the agency’s Q-Submission program. A pre-sub is a formal written request for written feedback from the FDA, which can be followed by a meeting. The agency’s written response is provided within 70 days, the meeting typically on day 70-75, and then it can take 30 days to receive revised final minutes from the meeting. FDA provides guidance on the Q-Submission program *here*.

Instead of embarking on that potentially 100-day route to get critical questions answered, Block’s client applied for a breakthrough designation and received it in 27 days.

“Our FDA interaction?” he said. “We didn’t have any. We submitted it, they got excited about it, and it took 27 days compared with 100 days to know where we stand. So for them it was absolutely, hands-down champagne uncorking time – absolutely worth it. Because they do have some things to talk to FDA about, and now they don’t have to do a 70-day pre-sub every time they have a question. They can do a sprint discussion.”

The FDA's *BDP guidance* says sprint discussions have the goal of reaching mutual agreement on a specific topic within an agreed-upon time period – “eg, 45 days.”

Data through 31 March 2023, published by the FDA in July, show that 67 devices, or 8.4%, have received marketing authorization out of 794 products awarded breakthrough status since the program’s inception. (Also see "*FDA Breakthrough Device Program Nears 800 Designations*" - Medtech Insight, 13 Jul, 2023.) Block speculated that some naysayers who question the BDP based on such figures may have limited experience working with startups.

“We had a client during the pandemic, we were excited, we were moving – fantastic. They contacted me last week for the first time in over a year. ‘We finally hired that person that could continue to do this, and we've got the design kinks, and we're finally ready to submit to TUV do

our electrical safety testing.'" While Block feared the worst, "now they're back alive."

A better question than how many breakthrough designees have reached the market could be, "How many were viable companies then? How many are viable companies now?" he said.

Companies' motivations for BDP participation should be considered as well. "We have one client that, sure, they have the exciting technology and everything. But their investors are looking for a win. And they've got other potential investors hanging on waiting. They need that win. And so they really are going at it for the recognition that will get them investor money to continue their development."

There could be numerous breakthrough sponsors in a similar boat. "They're trying to get that funding," Block said. "What if they don't? Well, then they have it on the wall, they have a nice accomplishment. And they fold up and they go on to their next venture."

Experiences May Vary

Block says the FDA's BDP guidance does a reasonably good job of detailing the program's ins and outs and setting stakeholder expectations.

He noted, however, that "not every [FDA] review group is going to interpret things exactly the same" or march to the same beat.

Block provided the example of a breakthrough device client who went through two sets of interactive questions from the agency within a month of being designated. "Day five, here's a set of questions. *Day 5?* We were waiting for day 30," Block said. After another set of questions, the client requested a meeting.

"Now we thought it would be maybe the lead reviewer and two people. [Instead], branch chief, person in charge of the division, and like five reviewers. So we had the entire team and two levels of management on what was being called an informal call outside the official process of the breakthrough device program."

Block added, "So yeah, there are differences in how excited they get. You know, this group may really want something like x on the market, and you just happen to come along, the people who have x."

If your company has y or z, Block provided a caveat: "Your experience may differ from the advertised experience."

More Carrots Than Weeds?

In Thompson's post last year, the attorney stated, "In my 35 years of working with medical

device companies, the program runs counter to everything I typically try to do in a device submission. My goal in nearly every device submission is to try to get through the FDA process with as little attention from FDA as possible."

In Thompson's view, the FDA is very good at what it is designed to do in accordance with its public health mission: regulate. "People can't be good at everything, but also there is a bit of a conflict between the mission of protecting patients and the objective of finding or discovering the least burdensome pathway through the agency," the attorney said.

He suggested that special attention from the FDA could result in recommendations for clinical trials, larger or more rigorous clinical trials, or more extensive risk assessments than the sponsor had envisioned.

Block acknowledged again that sponsor experiences may vary. That said, "we haven't had anyone yet that's been forced to do something that they don't think was reasonable in their data development plan," he said.

That includes his European client, which aims to submit a 510(k) to the FDA in the 2023 fourth quarter. Asked by the FDA when the company would be ready to pursue CE marking in Europe, the answer was, "Two years, 2025."

There's another talisman gleaming in the BDP's background: the prospect of speedy reimbursement. The US Centers for Medicare and Medicaid Services (CMS) is entertaining a framework wherein some majority of FDA-cleared breakthrough devices would be eligible for Transitional Coverage for Emerging Technologies (TCET), which could provide insurance coverage for three to five years to such devices while a National Coverage Determination is being finalized. (Also see "*Expanding Device Eligibility And Other Suggestions For CMS's TCET Pathway*" - Medtech Insight, 31 Aug, 2023.)