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Premarket Review of AI Medical Devices: FDA Hints at Larger Role for Regulatory Tool that Predicts How A Device May Learn and Evolve

A peculiar premarket decision and a draft letter on user fee negotiations reveal that FDA views predetermined change control plans as more than just a regulatory work-around for AI-powered medical devices.

Traditionally, the Food & Drug Administration's ("FDA") premarket review of medical devices assumes devices are static. A product is reviewed, cleared, or approved, and it stays the same unless the manufacturer files a new submission. But artificial intelligence ("AI") and machine learning ("ML") based devices challenge that assumption because they are designed to evolve and improve as they learn. And that creates tension with a regulatory system built around a snapshot-in-time review.

FDA has spent the last several years publishing guidances and building programs to create a regulatory framework to deal with this tension. Recently, FDA issued a draft commitment letter relating to user fee negotiations in which it lays out how it plans to fund its review of digital tech and AI devices.[1] Importantly, the draft letter highlighted that it planned more resources for staffing technical experts to review predetermined change control plans ("PCCP"). Relatedly, based on a de novo decision for an imaging device, FDA recently codified a peculiar new generic device listing for AI-based radiology products that is defined, in part, by the presence of an approved PCCP.[2]

Together, these developments tell a story about where FDA is headed.

THE PCCP FRAMEWORK

Mark Sorensen, owner of SyMed Inc., a Medicare-registered distributor of durable medical equipment, was convicted of conspiracy and offering kickbacks for payments made to advertising and marketing companies. These companies were involved in promoting orthopedic braces to Medicare patients. The government argued that these payments constituted illegal referrals under the Anti-Kickback Statute.

BUSINESS MODEL FOR ORTHOPEDIC PRODUCT SALES

A PCCP is a document submitted as part of a marketing authorization that describes in advance how a manufacturer plans to modify a device after it reaches the market. Think of it like asking for an approval, but with room to grow. This concept is what allows, for example, a ML-based imaging product to receive new data sets upon which to learn and assist in diagnoses, without having to seek new clearances or approval for each new data set added. PCCPs originated in a 2019 discussion paper on machine learning and AI based products,[3] and was ratified in 2022 when Congress added a new provision for PCCPs in the Federal Food, Drug, and Cosmetic Act.[4] FDA finalized guidance specific to AI-enabled devices in December

1. MDUFA Performance Goals and Procedures, Fiscal Years 2028 Through 2032, Draft Commitment Letter, Section IV.H, July 2026.PJM Interconnection, L.L.C., 195 FERC 61,209 (2026).

2. 91 Fed. Reg. 36522 (June 17, 2026) (final order classifying in class II generic device that are radiological machine learning-based quantitative imaging software with predetermined change control plan); De Novo Summary, Caption Interpretation Automated Ejection Fraction Software, DEN220063 (decision date Feb. 24, 2023).

2024 (updated August 2025)[5] and issued a broader draft guidance covering PCCPs for all medical devices in August 2024.[6]

A PCCP has three components: a description of the planned modifications, a modification protocol (explaining how the manufacturer will develop, validate, and implement the changes), and an impact assessment (explaining why the modifications will not compromise safety or effectiveness). Once FDA authorizes the PCCP as part of a marketing submission, the manufacturer is free to make any changes consistent with the PCCP. FDA's guidance frames this primarily as a "least burdensome" approach for manufacturers, reducing the need for repeated submissions.[7]

There are now a growing number of devices with authorized PCCPs. A search of FDA's various databases show that in the last two years FDA has approved or cleared over 200 product products with a PCCP, the vast majority of which are class II radiology and cardiovascular devices.

FDA'S RESOURCE COMMITMENT

The user fee draft commitment letter shows FDA putting real resources behind AI/ML device review. In discussing digital health, FDA commits to developing technical expertise in generative AI, ML, adaptive algorithms, virtual, mixed, and augmented reality, and wearables.[8] It explicitly states that this expertise "will also support [PCCP] reviews of AI-enabled devices and other digital health devices."[9]

FDA also commits to proactively engaging with industry on "high interest areas, such as PCCP, generative AI, adaptive algorithms, agentic AI, wearables, and other topics."[10] And it commits to promoting "approaches that balance premarket and postmarket evidence" for digital health devices. This signals a continued philosophical shift toward lifecycle regulation rather than point-in-time premarket gatekeeping.

The commitment letter will be the operational backbone of this shift. User fee negotiations are where FDA's review priorities become real because that is where the money goes. FDA is putting user fee funding behind hiring and training reviewers who can manage AI/ML submissions and PCCP reviews because the expectation is that FDA will increasingly rely on them as gatekeepers for what types of AI powered devices are allowed on the market.

A DEVICE DEFINED BY ITS REGULATORY FILING

As I mentioned above, FDA recently codified a new generic device type based upon a de novo decision (i.e. an approval for a novel class II product), and this is where things get interesting. In February of 2023, FDA approved a de novo application for the Caption Interpretation Automated Ejection Fraction Software. At the time, most of the press about this approval focused on the fact that this novel product made its way through the difficult de novo process and some mentioned that it was one of the first approvals involving a PCCP. But few, if any, outlets picked up on the more foundational issues that the resulting classification order establishes. In approving the de novo, FDA created a new generic device type called "radiological machine learning-based quantitative imaging software ***with predetermined change control plan.***"[11] That name is notable. Most device classifications describe a device by its technology and clinical function (think: "computed tomography x-ray system" or "nuclear electrocardiograph synchronizer"). This one includes "with predetermined change control plan" as part of the device type's identity.

The identification in the classification regulation states that the device's "design specifications include planned modifications that may be made to the device consistent with an established predetermined change control plan."[12] In other words, the PCCP is not just an accessory to the regulatory submission. It is written into the regulatory identity of the device itself.

What makes this more interesting is that Caption Health already had a 510(k) cleared device performing the same clinical function.[13] The de novo summary states that "the only change in this device compared to the [510(k) cleared device] was the addition of [the] PCCP."[14] Thus, the PCCP made it a different regulatory animal. Adding a document about how the device would change in the future was itself a change significant enough to warrant an entirely new classification.

3. FDA, *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD*), April 2, 2019, https://www.fda.gov/media/122535/download.
4. Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 3308 (adding § 515C to the Federal Food, Drug, and Cosmetic Act).
5. FDA, Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions, Final Guidance, August 2025, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence.
6. FDA, Predetermined Change Control Plans for Medical Devices, Draft Guidance, August 2024, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/predetermined-change-control-plans-medical-devices.
7. FDA, Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions, Final Guidance, August 2025.
8. MDUFA Draft Commitment Letter *supra* note 1 at 23-24.
9. *Id.*
10. *Id.*
11. 21 CFR § 892.2055 (emphasis added).
12. *Id.*
13. 510(k) Decision Summary K210747 (Jan. 19, 2022), https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210747.pdf.

We are not aware of any other generic device type that incorporates the presence of a PCCP into its regulatory identification. Indeed, many class II products are currently being cleared under existing generic device regulations after submitting a PCCP, and the agency has not required that they seek de novo reclassification for those product.[15] But this may be a signal worth paying attention to. If FDA continues down this path, we may see more device types defined not just by what they do or what technology they use, but by whether they plan to include a PCCP in their regulatory filing

THE PCCP AS A BENEFIT, NOT JUST A CONVENIENCE

Here is the second interesting finding from the Caption Health decision. The benefit/risk section of the de novo decision summary states: "The probable benefits of machine learning-based devices include the capability to improve their performance through iterative modifications, including learning from real-world data."[16] It then stated that the device "includes a [PCCP] which supports performance improvement through specific device modifications."[17]

FDA went further, concluding that "[t]he probable benefits of this machine learning-based device include plan to implement predetermined modifications that would improve the overall performance" and that "the implementation plan for the modifications authorized in the PCCP would allow enhancing the generalizability of the device and improving the performance for quantitative imaging applications while ensuring continued safety and effectiveness."[18]

Compare that to how FDA's guidance frames the intent of PCCPs. The guidance describes PCCPs as a means to avoid "necessitating additional marketing submissions for implementing each modification" and as "an approach that would often be least burdensome for manufacturers."[19] The guidance treats the PCCP as a regulatory efficiency tool. The de novo decision treats it as part of the clinical value proposition. Those are very different things with a meaningful distinction.

In the guidance, removing the PCCP does not change the device's benefit/risk profile; it just means more paperwork. In the de novo decision, the PCCP is an affirmative benefit because it enables the device to improve over time. The capacity to evolve is itself clinically valuable, and the PCCP is what makes that evolution both possible and controlled.

WHERE THIS IS HEADED

These signals suggest that FDA is interested in fundamental shifts in how it conceptualizes non-static products under the premarket review framework. The agency is building new infrastructure (user fee resources), new regulatory categories (§ 892.2055), and articulating a new conceptual rationale (PCCPs as benefits, not just burden reduction) for how it will handle products that will evolve once on the market.

If the Caption Health risk/benefit framing takes hold more broadly, it could reshape how sponsors approach PCCPs. Rather than treating a PCCP as optional regulatory paperwork that reduces the number of future submissions, sponsors might frame it as an integral feature that makes their device clinically superior to a static alternative. "Our device improves over time, and here is how" is a fundamentally different pitch than "we would like to avoid filing a new 510(k) every time we update the algorithm."

And if FDA continues creating device classifications that incorporate PCCPs into the device identity, the distinction between "the product" and "the regulatory framework governing the product" will continue to blur. A PCCP is, after all, a plan. It is a document about what will happen in the future. When that document becomes part of what the product is, the line between the product and its governance gets genuinely hard to draw.

The PCCP framework still has statutory limits. In general, the changes cannot expand the intended use or indications for use, and for class II products the changes must still be within the bounds such that the product remains substantially equivalent to its predicate. But within these bounds, the Agency appears to want maximize PCCP's utility by moving toward a regulatory model where the plan for how a device will change may be as important as what the device does on day one.

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14. De Novo Summary, DEN220063, at 4-5.
15. *See, e.g.*, 510(k) Decision Summary K261781 (July 24, 2026), https://www.accessdata.fda.gov/cdrh_docs/reviews/K261781.pdf.
16. De Novo Summary, DEN220063, Benefit/Risk Determination section.
17. *Id.*
18. *Id.*
19. PCCP Guidance, *supra* note 5, at 2.