Case Study

Caption Health

Caption Health's Regulatory Journey

Among the first authorized products with FDA's new Predetermined Change Control Plan (PCCP) is providing expanded access to cardiac care

The Story | A leading medical AI (Artificial Intelligence) company

Caption Health's mission is to help detect diseases early — when there is the highest potential for impact — by leveraging AI and ultrasound. They are a team of entrepreneurs, engineers, and clinicians who are committed to transforming care, expanding access, and reducing costs.

The Product | FDA authorized

Name: Caption Guidance (First cardiac ultrasound software that uses AI to guide users).

Intended use/Indication of use: The Caption Guidance software is intended to assist medical professionals in the acquisition of cardiac ultrasound images. Caption Guidance software is an accessory to compatible general purpose diagnostic ultrasound systems.

Caption Guidance software is indicated for use in two-dimensional transthoracic echocardiography (2D-TTE) for adult patients, specifically in the acquisition of the following standard views: Parasternal Long-Axis (PLAX), Parasternal Short-Axis at the Aortic Valve (PSAX-AV), Parasternal Short-Axis at the Mitral Valve (PSAX-MV), Parasternal Short-Axis at the Papillary Muscle (PSAX-PM), Apical 4-Chamber (AP4), Apical 5-Chamber (AP5), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).

FDA class: Class II Medical Device

Product code: QJU

Regulation section: 21 CFR 892.2100 - Radiological acquisition and/or optimization guidance system

FDA Regulatory Pathway: De Novo pathway (DEN190040)

The Value | Regulated vs non-regulated

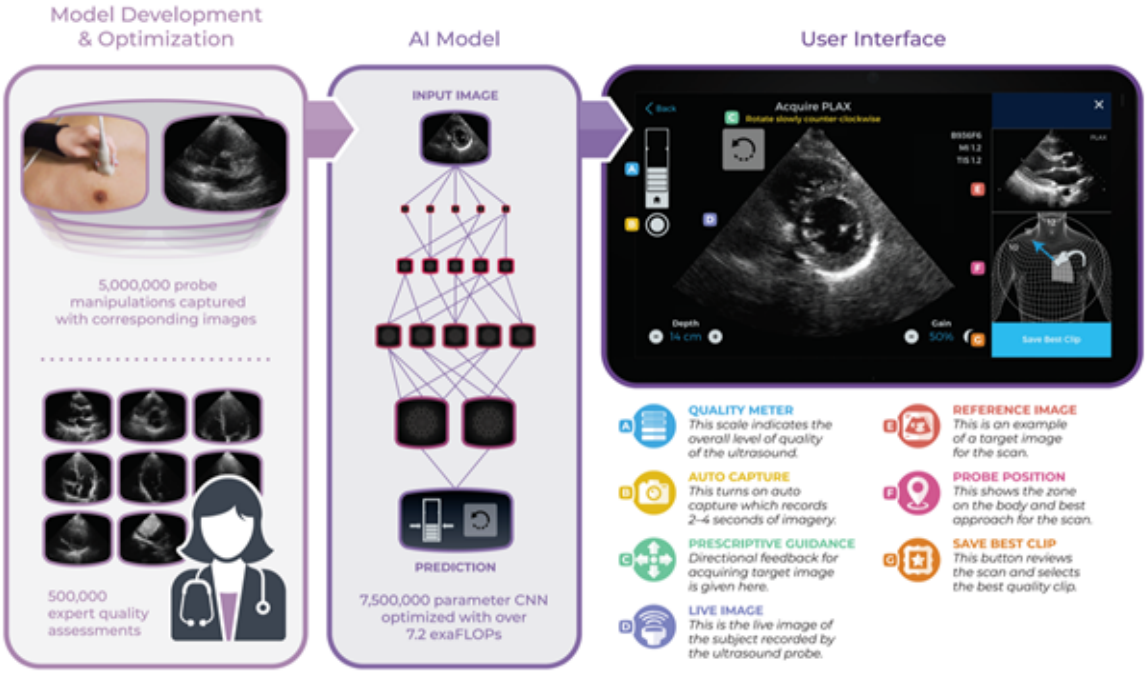
As the Caption Guidance Software met the FDA definition of a medical device, it therefore fell under the FDA regulatory requirements.

The Strategy | Fit-for-purpose

Innovative products often pose unique scientific and regulatory questions that have not been posed previously. The key to business success of Caption Health was to identify viable commercial and regulatory strategies before they committed to large amounts of time, capital, and resources for product development.

They first developed a holistic strategy internally that was iterative and cross-functional involving expert inputs and reviews from multiple disciplines. It began with strategic planning activities early in the development process – with each function contributing toward a document called the “Product Brief”. This document is part of the Discovery and Concept phase, in which clinical, product, and commercial teams identify user needs, industry trends, reimbursement pathways and product requirements to inform the development process, while engineering and regulatory teams weigh-in for potential options to:

1. Adequately meet user needs and
2. Identify the least complex regulatory pathways resulting in the fastest time to market (commercialization).

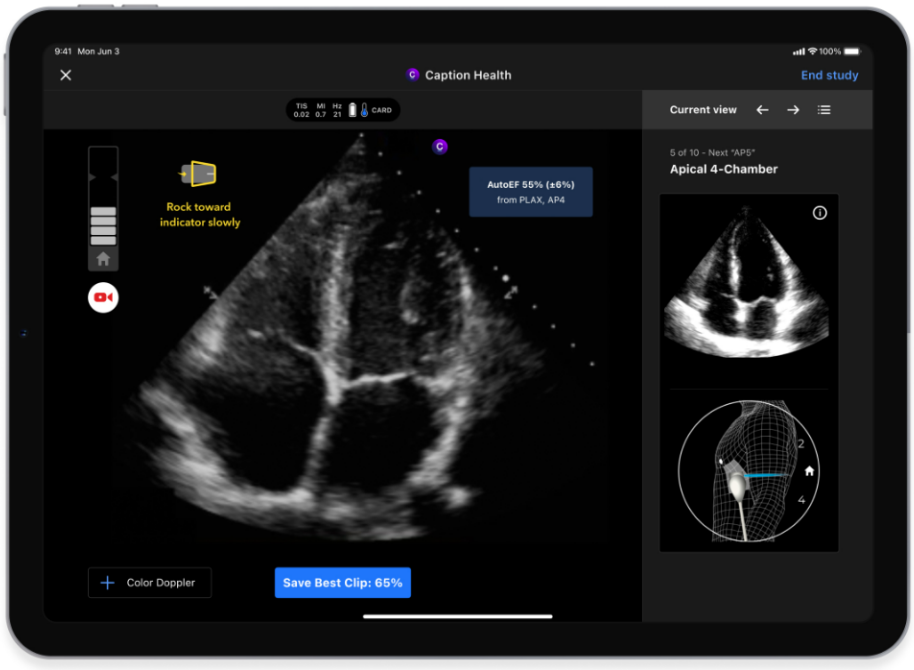


Source: JAMA Cardiology[1] (February 2021)

[1] Narang A, Bae R, Hong H, et al. Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use. JAMA Cardiol. 2021;6(6):624–632. doi:10.1001/jamacardio.2021.0185

As part of the regulatory strategy, Caption Health identified options for engaging with the FDA, which included pre-submission meetings (including a physical demo of the software with the FDA during a face-to-face meeting) as well as applying for breakthrough designation, given the novelty of the Guidance Software.

As part of the De Novo submission, Caption Health obtained regulatory approval for a Predetermined Change Control Plan (PCCP). The PCCP allows manufacturers to make certain changes without needing a new regulatory submission. This plan would include the types of anticipated modifications—referred to as the "SaMD Pre-Specifications"—and the associated methodology being used to implement those changes in a controlled manner that manages risks to patients — referred to as the 'Algorithm Change Protocol.' In this approach, the FDA expressed an expectation for transparency and real-world performance monitoring by manufacturers that could enable the FDA and manufacturers to evaluate and monitor a software product from its premarket development through postmarket performance. This framework would enable the FDA to provide a reasonable assurance of safety and effectiveness while embracing the iterative improvement power of AI and machine learning-based software as a medical device.



Caption Health has used its approved PCCP to port the guidance software to new hardware platforms, as well as optimize its algorithms without needing additional regulatory submissions, saving both time and money.

The Influencing Factors | Building it right

Caption Health considered several factors in building the regulatory strategy such as identifying target user populations to inform the intended use; how the product would fit within existing and potentially future clinical pathways; and more. The target user also aided in the prioritization of product features e.g., Auto-Capture and Prescriptive Guidance.

Caption Health was not aware of similar predicate devices on the market, and based on the risk profile of the device, and intended user base, they decided that the De Novo pathway would be the most suitable regulatory pathway.

As part of its regulatory strategy, Caption Health successfully applied for breakthrough designation, which is granted to devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The Breakthrough Devices Program gave Caption Health an opportunity to interact with the FDA's experts to efficiently address topics throughout the development process, as well as prioritized review of its De Novo submission.

The Impact | Value in ripple effects

The Caption Health Guidance Software is the first and only guidance software which enables any healthcare provider that is not an expert in doing cardiac ultrasound exams, such as a registered clinic nurse, to perform diagnostic quality echocardiograms (echos). Echos are one of the most widely used diagnostic tools in the diagnosis and treatment of heart disease. They are typically performed by cardiac sonographers, which can take two years of training. There is currently a shortage of diagnostic and medical sonographers in the U.S. with a projected growth of positions by 15% through 2031. Thus, the hope is that the Caption Guidance software can help with the backlog and speedup diagnosis.

The breakthrough designation for Caption Guidance Software already meant that the potential for outcomes was understood and as such, only the cost requirement had to be demonstrated. This opened some reimbursement pathways with the Centers for Medicare & Medicaid Services (CMS) - enabling Caption Health to obtain a New Technology Add-on Payment (NTAP) designation.

> "Today we do breast cancer screening and colon cancer screening for earlier detection, but the leading cause of death in the world — heart disease and heart failure — is a reactive business. By lowering the barrier to acquire the data that's needed and a picture of the heart, we actually can do this more routinely in early care for patients that are at risk."
>
> **Steve Cashman,** CEO at Caption Health

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