Caption Health

Expanding access to cardiac care with the first FDA-authorized AI ultrasound software

About Caption Health

Caption Health, now part of GE HealthCare (acquired in Feb. 2023), is on a mission to help detect diseases early—when there is the highest potential for impact—by leveraging AI and ultrasound. It is a team of entrepreneurs, engineers, and clinicians committed to transforming care, expanding access, and reducing costs.

The opportunity

- Echocardiograms are one of the most widely used diagnostic tools for heart disease. They are typically performed by cardiac sonographers, who require multiple years of training. Today, there is a shortage of diagnostic and medical sonographers in the U.S.
- Caption Health **saw an opportunity to build a novel product** to assist medical professionals in acquiring cardiac ultrasound images.

The challenge

- Innovative cardiac AI-enabled software products can pose unique regulatory challenges. It was important for Caption Health to **ensure product safety and effectiveness** while embracing the iterative nature of AI-based software as a medical device.
- To account for forthcoming product changes upfront, Caption Health identified target user populations, the product's fit within existing and potentially future clinical pathways, and other impacts to inform the intended use.

The approach

- Caption Health **identified options for engaging with the FDA**, which included a series of pre-submission meetings (including a physical demo of the software during a face-to-face meeting) and applying for breakthrough designation status, given the novelty of the product.
- Using the De Novo pathway, Caption obtained the first regulatory approval for a predetermined change control plan (PCCP), which allows manufacturers to make specific changes to a product without a new regulatory submission. They used the PCCP to port their software to new hardware platforms and optimize product algorithms **without additional regulatory submissions**, thus saving time and money.

The success

- ✔ Caption Health received the **first FDA-authorized cardiac ultrasound AI software clearance** under the FDA's breakthrough program.
- ✔ The breakthrough designation status opened **reimbursement pathways** with the Centers for Medicare & Medicaid Services (CMS) - enabling Caption Health to obtain a new technology add-on payment (NTAP) designation.
- ✔ Following their regulatory and reimbursement successes, GE HealthCare acquired Caption Health.

> " We are incredibly proud of the technology we have built, and together with GE HealthCare, we look forward to bringing this technology to more patients across the globe. Combining our AI applications with GE HealthCare's ultrasound devices will help accelerate our mission to detect disease earlier when an easily obtained diagnostic image can be a great equalizer to health quality and outcomes to ultimately help us reduce costs and enhance care."
>
> **— Steve Cashman**
> *Former Chief Executive Officer, Caption Health*

Want to learn about the full regulatory journey of Caption Health? Check out the detailed case study here.

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