

**Category**

Best Digital Health Solution

**General Information****Company Name \***

RapidAI

**Number of employees \***

201-500

**Turnover and/or Funding**

N/A

words remaining :

500

**Product/Solution Name \***

Rapid Aneurysm

**Corporate Name \***

RapidAI

**Date of Approval \***

2023-07-27

**Indications \***

Rapid Aneurysm consists of Rapid Aneurysm Triage and Notification, and Rapid Surgical Preview.

Rapid Aneurysm Triage and Notification is a radiological computer-assisted triage and notification software device for analysis of CT images of the head. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected saccular aneurysms during routine patient care. Rapid Aneurysm utilizes an artificial intelligence algorithm to analyze images and highlight studies with suspected saccular aneurysms in a standalone application for prioritizing or triaging study lists in parallel with ongoing standard of care.

Rapid Surgical Preview provides 3D segmentation models and tools to visualize, measure, and track quantitative and morphological changes of vascular structures such as vessels, aneurysms, and other anomalies. Pre-set measurements and annotations are provided for clinician review/verification. Clinicians may also computationally model the placement and deployment of neurointerventional devices to aid in the assessment and treatment planning of unruptured intracranial aneurysms.

General functionalities are provided, such as:

- Segmentation of neurovascular structures
- Automatic centerline detection
- Visualization of CT, MR, and 3DRA scan images for 2D review and 3D reconstruction
- Measurement and annotation tools
- Reporting tools

Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

words remaining :

273

### Therapeutic Areas \*

Neurovascular imaging: AI-driven support for the detection and surveillance of brain aneurysms

words remaining :

488

\*Kindly clearly label your files with company name and asset name.

Attached Files:

- [RapidAI\\_FDANotification.pdf](#)

### Background information and need for drug / device

(please be as specific as possible in your description; limit 500 words)

Over 6 million Americans live with an unruptured brain aneurysm, yet many go undiagnosed until it's too late. Traditional CTA interpretation relies on overburdened radiologists identifying small, often subtle abnormalities, vulnerable to human variability, especially during off-hours or under heavy workload.

Rapid Aneurysm is designed to catch what others might miss. It uses AI to automatically flag suspected saccular aneurysms on CTA scans and provides rich, 3D visualizations to support earlier diagnosis and more confident monitoring.

But a significant impact comes after detection. Aneurysms rarely grow in neat, symmetrical ways, meaning that simple diameter measurements on 2D images often fail to capture meaningful change. Rapid Aneurysm delivers volumetric, morphologic, and spatial growth insights in three dimensions, giving clinicians a precise, complete view of aneurysm evolution over time. In a real world cohort of 5,000 aneurysms, a study demonstrated that volumetric analysis with Rapid Aneurysm outperformed traditional 2D linear measurements in identifying growth among aneurysms that later ruptured during conservative management. Rapid's deep clinical AI detected enlargement in 100% of ruptured cases, including two missed by expert manual review, highlighting the critical role of volumetric data in accurately assessing rupture risk and guiding timely intervention. (1)

This clarity is more than convenience; it's critical. Even subtle, overlooked growth can signal rupture risk. One missed change can mean the difference between intervention and a devastating bleed.

In a large-scale real-world study(2), Rapid Aneurysm achieved 92.5% sensitivity and 96.4% specificity for detecting aneurysms  $\geq 3\text{mm}$ , identifying 23% more clinically significant aneurysms than initial radiology reports.

By combining AI-driven precision with automated, reproducible visualization tools, Rapid Aneurysm enhances every stage of care-from early detection to risk stratification to confident decision-making. It empowers providers to shift from reactive to predictive care, and gives patients a better chance at intervention before it's too late.

words remaining :

203

\*Kindly clearly label your files with company name and asset name.

Attached Files:

- [Sahlein\\_etal\\_2022\\_Artificial intelligence aneurysm measurement tool finds growth in all aneurysms that ruptured during conservative management.pdf](#)
- [RapidAI\\_BackgroundStudy1.pdf](#)
- [RapidAI\\_BackgroundStudy2.png](#)

### **History of the development of the solution/product \***

**(please be as specific as possible in your description; 500 words)**

The genesis of Rapid Aneurysm stemmed from a profound clinical need: to fundamentally transform how intracranial aneurysms are identified, characterized, and meticulously prepared for intervention. In a field where precision and timeliness are paramount, the traditional workflow presented inherent challenges, often leading to delays and variability in critical patient care decisions. Our vision was to dismantle these barriers by harnessing the power of artificial intelligence, delivering a solution that is not merely technical but truly transformative for neurovascular specialists and their patients.

This innovation is built upon the robust foundation of the Rapid Platform, engineered for high performance and intuitive use in medical image processing and analysis. The platform's core strength lies in its ability to automatically process DICOM data from various imaging modalities, apply advanced analytical modules, and deliver actionable insights directly to clinicians.

A peer-reviewed study published in Journal of Stroke and Cerebrovascular Diseases demonstrated that Rapid Aneurysm achieved 95% sensitivity and 100% specificity in detecting unruptured cerebral aneurysms on CTA, outperforming manual interpretation. Using a dataset of 60 aneurysms across 51 patients, the study validated Rapid's AI accuracy against consensus from three expert neuroradiologists, confirming its clinical reliability and precision in high-stakes diagnosis.(1) A separate investigation quantitatively compared Rapid's automated annotations with blinded, independent neuroradiologist measurements obtained from Digital Subtraction Angiograms (DSA), the recognized clinical benchmark for high-resolution contrast-enhanced imaging. This comparison demonstrated excellent correlation (0.93-0.98) across neuroradiologist-measured aneurysm height, width, and neck dimensions.(2) This level of performance meets and exceeds diagnostic thresholds for augmenting clinical workflows in high-stakes environments.

In a large-scale retrospective analysis of 11,694 consecutive CTA studies, Rapid Aneurysm significantly outperformed clinical radiologists in detecting intracranial aneurysms, identifying 23% more aneurysms than radiologists alone-460 cases compared to 373. Remarkably, Rapid Aneurysm detected 150 aneurysms that were missed by radiologists, while radiologists identified only 63 that the AI missed. This delta demonstrates not only high accuracy but also critical real-world value: patients who otherwise might not have been diagnosed in time could now be triaged for life-saving intervention.(3)

With this product, RapidAI has introduced not just a technical tool, but a new clinical paradigm-one where AI elevates standards of care, helps reduce missed diagnoses, and ultimately helps prevent devastating outcomes. In the fight against finding intracranial aneurysms, and acting on them precisely at the right time, Rapid Aneurysm stands as a beacon of what's possible when deep clinical insight meets cutting-edge AI.

words remaining :

103

\*Kindly clearly label your files with company name and asset name.

Attached Files:

- [RapidAI Clinical\\_study1.pdf](#)
- [RapidAI Clinical\\_study2.pdf](#)
- [RapidAI Clinical\\_study3.png](#)

### **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition \***

As imaging procedures continue to rise across the healthcare system, radiologists are tasked with reviewing more studies under tighter time constraints-creating more opportunities for missed findings, fatigue, and confirmation bias during interpretation.

Rapid Aneurysm is redefining what AI-driven clinical decision support means in neurovascular care, not by simply flagging suspected aneurysms, but by providing the detailed, high-fidelity data that enables smarter, more confident clinical decisions. Traditional diagnostic tools might point to an abnormality. Rapid Aneurysm goes further, delivering automated 3D visualizations, precise measurements, and longitudinal comparisons that are exceptionally difficult to obtain manually. These outputs reduce variability, clarify subtle changes over time, and support clinicians in deciding not just if an aneurysm exists, but when and how to act. For example, a recent publication validated Rapid's superior accuracy in aneurysm volume determination, highlighting its potential to optimize and preplan aneurysm packing density ahead of surgical intervention.(1)

The ability to visualize the aneurysm in multiple planes and dimensions-paired with accurate size and location data-adds a new layer of diagnostic confidence. Subtle morphologic changes that might otherwise be missed in follow-up scans can now be easily tracked and monitored. This allows physicians to differentiate stable aneurysms from those that warrant closer attention, transforming episodic decision-making into proactive, longitudinal care. Just as importantly, it gives patients something they rarely receive with this diagnosis: reassurance. Knowing that their condition is being closely monitored with the most advanced technology available allows them to live more freely, with a

mitigated fear of the unknown. It builds trust, strengthens communication, and helps transform a life-altering diagnosis into a manageable condition.

In one real-world example, Rapid Aneurysm identified a missed aneurysm that had gone undetected in a prior scan—an oversight that ultimately led to a rupture, patient fatality, and a malpractice lawsuit exceeding \$1 million. The case underscores both the devastating human cost of missed diagnoses and the protective value of advanced diagnostic tools. With Rapid Aneurysm in place, that rupture could have been prevented, and the patient's outcome, and provider's risk, dramatically different.

The broader implications of this technology go beyond aneurysms. Rapid Aneurysm sets the stage for future AI solutions (some of which we're seeing already) that can track, quantify, and communicate disease progression with this same level of clinical precision and clarity. It is a model for how AI can serve not just as a detector, but as a decision-making companion.

Rapid Aneurysm doesn't just help catch what others miss. It helps ensure that every patient gets the right care, at the right time, with confidence. No other solution on the market combines deep clinical AI, volumetric change detection, and triage-ready deployment to address one of the most life-threatening, and often silent, neurovascular risks.

words remaining :

51

\*Kindly clearly label your files with company name and asset name.

Attached Files:

- [RapidAI\\_Innovation\\_Study1.pdf](#)

**Please provide appropriate references (PubMed, Abstract, Website) \***

<https://www.rapidai.com/neurovascular/aneurysm>  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf23/K230074.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf23/K230074.pdf)  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf17/K171534.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171534.pdf)  
<https://aans2025.eventscribe.net/fsPopup.asp?PresentationID=1584977&mode=presInfo>  
<https://pmc.ncbi.nlm.nih.gov/articles/PMC8673900/>  
[https://www.strokejournal.org/article/S1052-3057\(22\)00384-6/abstract](https://www.strokejournal.org/article/S1052-3057(22)00384-6/abstract)  
<https://jnis.bmj.com/content/15/8/766.long>  
[https://journals.sagepub.com/doi/10.1177/15910199231222676?url\\_ver=Z39.88-2003&rfr\\_id=ori:rid:crossref.org&rfr\\_dat=cr\\_pub%20%200pubmed](https://journals.sagepub.com/doi/10.1177/15910199231222676?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed)  
<https://www.sciencedirect.com/science/article/pii/S1878875024019636?via%3Dihub>  
<https://pmc.ncbi.nlm.nih.gov/articles/PMC12134790/>  
<https://www.youtube.com/watch?v=vrmQ2TGMvC0&pp=ygUHcmFwaWRhaQ%3D%3D>  
[https://www.youtube.com/watch?v=adGt8B8\\_8r4&pp=ygUHcmFwaWRhaQ%3D%3D](https://www.youtube.com/watch?v=adGt8B8_8r4&pp=ygUHcmFwaWRhaQ%3D%3D)  
<https://www.youtube.com/watch?v=WRZE9nm1mxU&pp=ygUHcmFwaWRhadIHCQnDCQGhKiGM7w%3D%3D>  
<https://www.youtube.com/watch?v=aWaa7oEdCtE&pp=ygUHcmFwaWRhaQ%3D%3D>  
[https://www.youtube.com/watch?v=QXa8UZdlx\\_0&pp=ygUHcmFwaWRhaQ%3D%3D](https://www.youtube.com/watch?v=QXa8UZdlx_0&pp=ygUHcmFwaWRhaQ%3D%3D)  
<https://www.youtube.com/watch?v=BrOWdOBtzR8&pp=ygUHcmFwaWRhaQ%3D%3D>

\*Kindly clearly label your files with company name and asset name.

Attached Files:

- [RapidAICaseStudy.pdf](#)
- [RapidAI\\_Casestudy2.pdf](#)
- [RapidAI\\_ClinicalPoster\\_AANS.pdf](#)