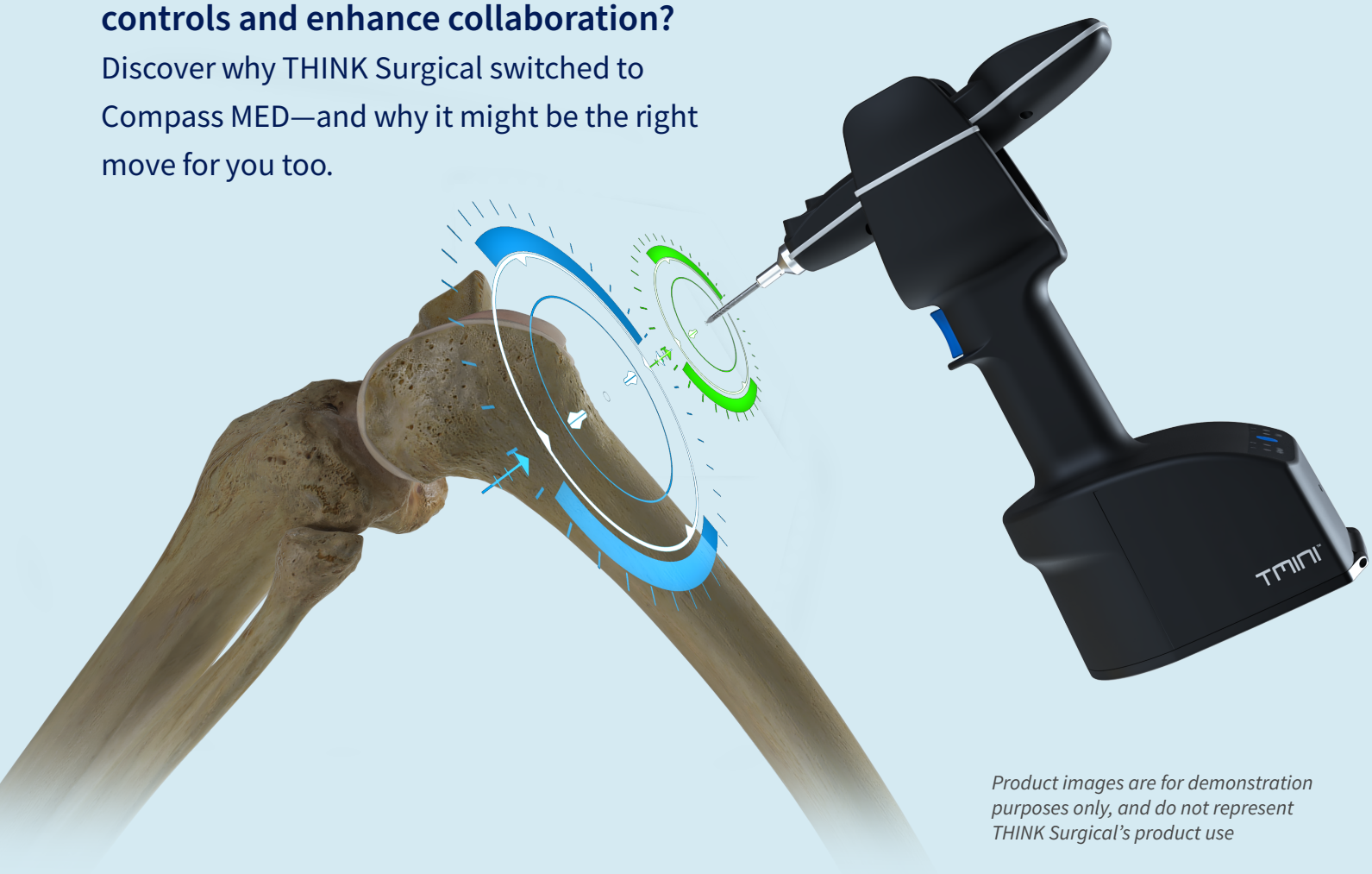
THINK Surgical Consolidates Design Controls and Quality Management with Cognition's Compass® MED

CASE STUDY: THINK SURGICAL

Is your organization missing opportunities to accelerate design controls and enhance collaboration?

Discover why THINK Surgical switched to Compass MED—and why it might be the right move for you too.



Product images are for demonstration purposes only, and do not represent THINK Surgical's product use

COGNITION®
NAVIGATING PRODUCT DEVELOPMENT

THINK®
SURGICAL

OVERVIEW

THINK Surgical, Inc., is a privately held U.S.-based technology innovator that develops and markets orthopedic robots. The organization is committed to nurturing new ideas and creating open platform orthopedic robotics that support implant brands from multiple manufacturers, enabling surgeons to connect their implant choice to a single robotic operating system. THINK Surgical collaborates with healthcare professionals around the world to improve the lives of those suffering from advanced joint disease with precise, accurate, and intelligent technology.

As part of its commitment to innovation and quality, THINK Surgical has partnered with Cognition® Corporation for structured medical device design and development support since 2019—and implemented Cognition's newest structured data and design controls solution, Compass® MED, in November 2024.

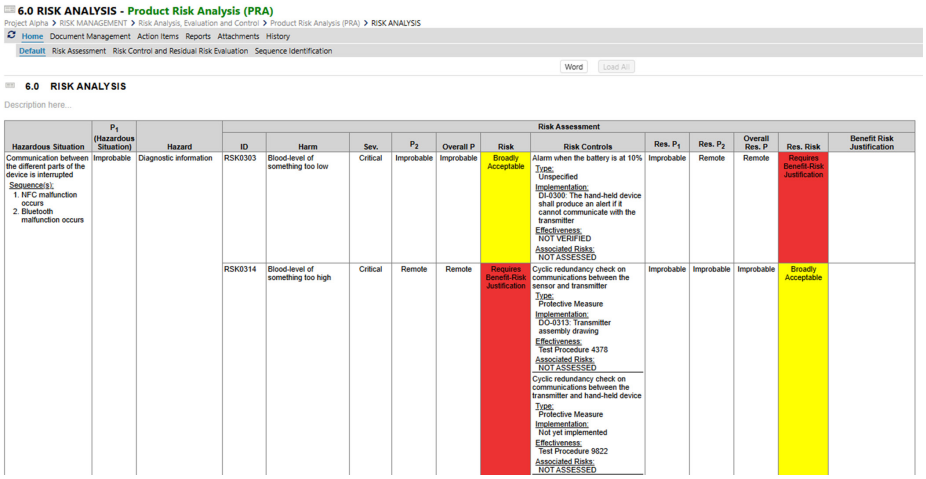
CHALLENGE

In August 2023, THINK Surgical began searching for a solution that would enable it to consolidate its multiple design controls and quality management processes into one centralized, SaaS platform. For the past several years, the organization had relied on two separate systems, including Cognition's Cockpit® Enterprise solution as well as a leading competitor's solution. One THINK Surgical product team was using Cockpit; the other team was using the competitor's solution.

"With the competitor's solution, we were finding that it was difficult to enforce a design structure or hierarchy without a lot of intentional subject matter experts involved," said Terence Carmichael, Jr., Lead Systems Engineer at THINK Surgical. "There weren't really any guardrails that would, for example, prevent someone from linking or tracing things in a manner that may not be logical or beneficial." In addition, Carmichael added, there weren't very many guardrails related to setting up or building a new project, which raised concerns related to consistency and quality.

When THINK Surgical approached Cognition about its desire to consolidate solutions—and address some of its challenges with the competitor's solution—Cognition shared that they would be releasing Compass MED in late 2024. This out-of-the box, cloud-based, SaaS solution would combine core features from Cognition's previous solutions, like Cockpit, which is deployed at the largest MedTech companies, with additional efficiency and quality enhancing capabilities, as well as an improved UX/UI.

Compass MED was very compelling, said Carmichael. "Compass MED would allow us to implement a design hierarchy. It was streamlined and baked in. We also felt that the out-of-the-box solution would support a more efficient process for design tracing and risk management."



6.0 RISK ANALYSIS - Product Risk Analysis (PRA)

Project Alpha › RISK MANAGEMENT › Risk Analysis, Evaluation and Control › Product Risk Analysis (PRA) › RISK ANALYSIS

Home | Document Management | Action Items | Reports | Attachments | History

Default | Risk Assessment | Risk Control and Residual Risk Evaluation | Sequence Identification

Word | Load All

6.0 RISK ANALYSIS

Description here...

Hazardous Situation	P_1 (Hazardous Situation)	Hazard	Risk Assessment											Benefit Risk Justification
			ID	Harm	Sev.	P_2	Overall P	Risk	Risk Controls	Res. P_1	Res. P_2	Overall Res. P	Res. Risk	
Communication between the different parts of the device is interrupted Sequence(s): 1. NFC malfunction occurs 2. Bluetooth malfunction occurs	Improbable	Diagnostic information	RSK0303	Blood-level of something too low	Critical	Improbable	Improbable	Broadly Acceptable	Alarm when the battery is at 10% Type: Unspecified Implementation: DI-0300: The hand-held device shall produce an alert if it cannot communicate with the transmitter Effectiveness: NOT VERIFIED Associated Risks: NOT ASSESSED	Improbable	Remote	Remote	Requires Benefit-Risk Justification	
			RSK0314	Blood-level of something too high	Critical	Remote	Remote	Requires Benefit-Risk Justification	Cyclic redundancy check on communications between the sensor and transmitter Type: Protective Measure Implementation: DO-0313: Transmitter assembly drawing Effectiveness: Test Procedure 4378 Associated Risks: NOT ASSESSED Cyclic redundancy check on communications between the transmitter and hand-held device Type: Protective Measure Implementation: Not yet implemented Effectiveness: Test Procedure 9822 Associated Risks: NOT ASSESSED	Improbable	Improbable	Improbable	Broadly Acceptable	

Sample Product Risk Analysis

Since Compass MED would not be released until later 2024, THINK Surgical knew they would need to wait a few months before making the transition. Still, they felt it would be worth the wait, particularly after they completed a thorough evaluation of the various solution options available in the market. This included areas such as deployment logistics and timing, design inputs, test environment, risk management, and usability.

> *"We knew Compass MED would help support our strategic goals by making it easy for systems, tests, and design teams to collaborate and iterate across the product development lifecycle. It would keep everyone connected, enhance traceability, and streamline regulatory submissions."*
>
> Terence Carmichael, Jr., Lead Systems Engineer, THINK Surgical

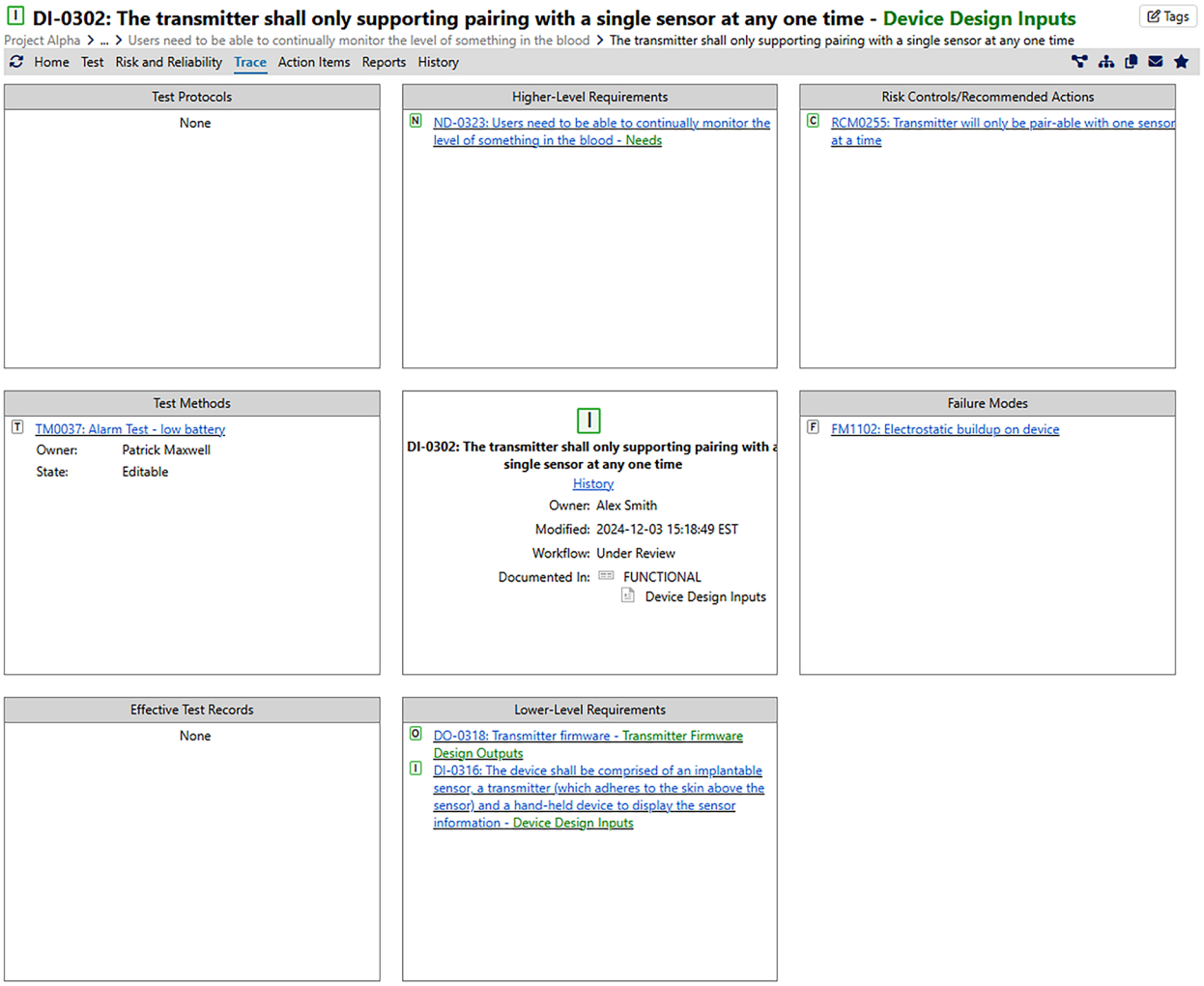
Sample Submission Ready Design and Development Plan

SOLUTION

Compass MED, released by Cognition in September 2024, is an intelligent structured data and design controls solution specifically designed for medical device manufacturers. In addition to guided design controls, real-time traceability, submission-ready documents, and change once, update everywhere functionality, it offers efficiency and quality enhancing capabilities, such as:

- Connected requirements, risk, and test management
- Guided compliance templates (ISO 14971, IEC 62366, ISO 13485, 21CFR 820, and (EU) 2017/745)
- Tabular data-centric workspaces and document-centric formats
- Change once, update everywhere functionality using structured data elements
- Built-in workflows with authoring, reviewing, and releasing information
- Automated trace matrices in real time
- Comprehensive risk management
- Collaborative review process
- Detailed audit logs
- Instant exports of submission-ready documents in the exact format required

"Compass MED is a comprehensive solution that enables us to capture, organize, and track critical information throughout the product lifecycle, ensuring compliance and streamlining submissions," said Joel Zuhars, Vice President of Innovation at THINK Surgical. "Engineers from multiple product silos can all design, iterate, challenge test cases, and share ideas in one place."



Sample Item Level Trace

> *"Compass MED is different from other solutions because it allows for a flexible design controls environment where we're able to scale up or scale down the levels of a given product design while still following similar design hierarchies that other engineers across different disciplines can understand and follow."*
>
> Terence Carmichael, Jr., Lead Systems Engineer, THINK Surgical

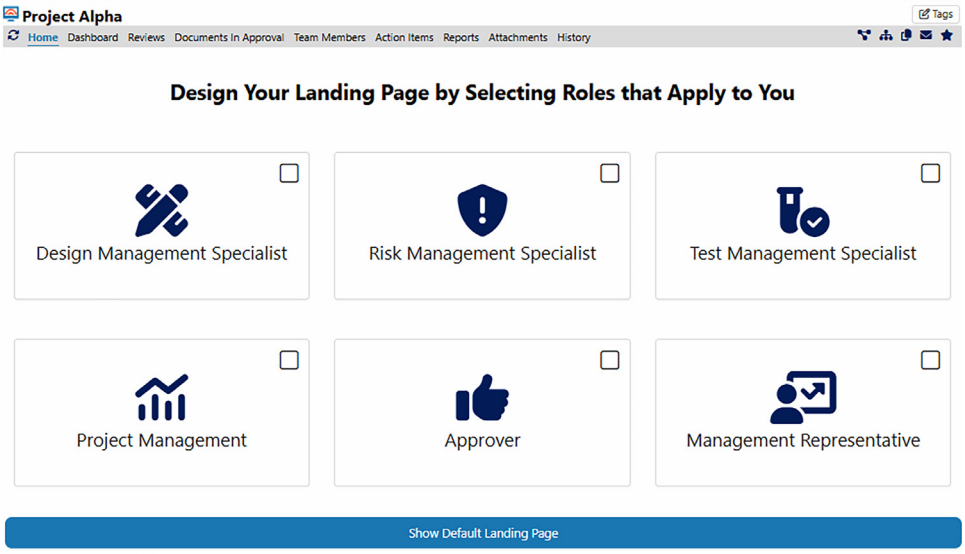
RESULTS

Compass MED is providing multiple benefits to THINK Surgical, said Carmichael. "We can easily collaborate on requirements and test cases and produce automated traceability matrices," he noted. "This is expected to expedite our verification and validation test cycles and help us generate critical documents needed for regulatory submissions faster."

Sample Product Design Management

While transitioning to a new structured data and design controls solution naturally takes time and effort, Carmichael said the journey has been well worth it for THINK Surgical. He specifically highlighted the efficiency enhancing capabilities of built-in design hierarchies, automated tracing, and guided design controls and requirements as top benefits. In addition, he said, Compass MED makes it easier to identify errors or redundancies, such as duplicate requirement inputs.

Zuhars agreed, noting that Compass MED will support THINK Surgical as the organization continues to scale and grow its products. "It's a cloud-based deployment, so adding users or divisions or groups is easy. It was key, as part of our solution selection process, to know that Compass MED will support our current and future needs."



Role Based Homepage Selection

> *"Transitioning to Compass MED has been a very collaborative, process. They've given us a solution that helps improve and accelerate our development lifecycles, but they've also taken our wants and future goals into account to make small modifications and changes that address our unique needs."*
>
> Joel Zuhars, Vice President of Innovation, THINK Surgical

A Collaborative and Comprehensive Partnership

While the THINK Surgical team was excited about transitioning to Compass MED, they had some initial concerns about the impact of the transition on their legacy data. Cognition, however, has ***supported them at every step***, bringing legacy data into the new solution for THINK Surgical, helping them set up templates most relevant to their previous workflows and needs, and providing numerous training opportunities to ensure all users are comfortable and ready to transition, said Carmichael. "They've worked very closely alongside us and are committed to helping us succeed."

ABOUT THINK SURGICAL, INC.

THINK Surgical, Inc., is a privately held U.S.-based technology innovator that develops and markets orthopedic robots. THINK Surgical robots are open platforms providing support for implant brands from multiple manufacturers, enabling the choice of implant to be driven by the surgeon. THINK Surgical actively collaborates with healthcare professionals around the globe to refine our orthopedic products, improving the lives of those suffering from advanced joint disease with precise, accurate, and intelligent technology. For additional product information, visit www.thinksurgical.com. TMINI and THINK Surgical are registered trademarks of THINK Surgical, Inc.

ABOUT COGNITION CORPORATION

Cognition Corporation specializes in product development and compliance solutions for the life sciences industries. Our solutions focus on enhancing efficiency, quality, and compliance throughout the development process. For medical device companies, Cognition offers a structured data and design controls solution, Compass MED, that helps meet regulations faster with real-time traceability, guided design controls, and change once, update everywhere functionality – turning manual and disconnected data into structured submissions that enable them to get to market faster. Unlike other solutions that simply replicate traditional documents and spreadsheets, Cognition takes a structured data approach so you can easily build relevant connections between data items, automatically create complex trace matrices and data tables, and export formatted documents instantly – offering a more efficient and integrated solution.

Cognition is shifting the data management landscape for life sciences product development from a static, document-based approach to a dynamic, information-driven approach helping to streamline and alleviate the administrative burden of product development documentation. Further information about Cognition Corporation can be found at www.cognition.us.