Somnera Receives FDA Clearance in Record Time With the Help of Galen Data

Somnera (formerly Fresca Medical) developed an innovative low-flow positive airway pressure system for patients with obstructive sleep apnea (OSA). The company's patented SmartValve™ technology provides an alternative to traditional CPAP machines by offering a breakthrough breathing experience for those who struggle with OSA. Somnera's valve allows for a smaller, compact device and components while also eliminating the need for a humidifier. The Somnera™ System provides sleep data monitoring through the SleepBridge App and Cloud platform, and has the ability to wirelessly transmit the data to medical professionals and healthcare providers.

Galen Data

The challenge of obtaining regulatory approval and expediting go-to-market

The experienced team at Somnera knew device connectivity was necessary for their machine to allow medical professionals to track patient use and monitor patient adherence remotely. Somnera did not possess the technological resources to build their own cloud platform or app. Working within a tight timeline prior to FDA submission, Senior Director of Business Development, Ed McCarthy, said "We knew that building it ourselves was outside of our capabilities... and we needed to find the right partner for the job with a successful track record and expertise in medical device technology."

Galen Data's comprehensive, turnkey solution

The Galen Cloud™ accelerated Somnera's time-to-market and provided the compliant solution needed for FDA approval. The Galen Data team supplied experts in software and regulatory compliance who were committed to Somnera's device connectivity and timeline: "Galen offered a true one-stop-shop with in-house expertise in all of the disciplines needed to complete the job — which made them an attractive partner for us," said McCarthy.

With the Galen Cloud™, Somnera was able to have a fully-operational cloud platform and app within a matter of months instead of years. The platform allows the Somnera™ System to wirelessly collect, store, share, and quickly analyze patient data.
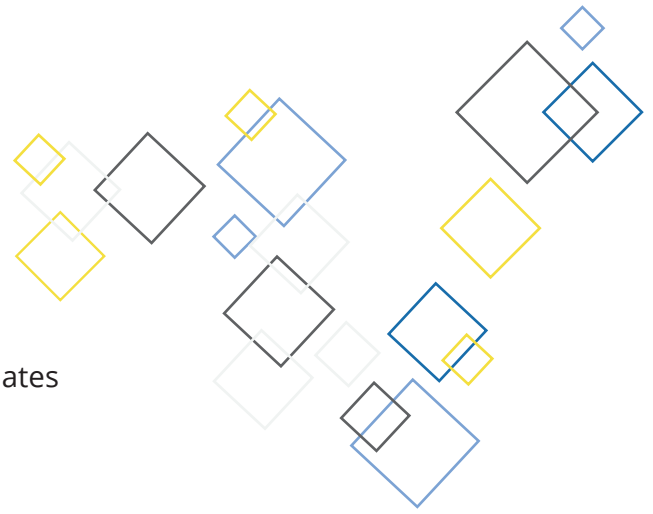
> *Without Galen Data, we wouldn't have been able to develop our fully-connected SleepBridge data exchange and submit to the FDA within our aggressive timeline.*
>
> Ed McCarthy, Senior Director of Business Development, Somnera

75%
Time savings and speed to submission

Increased accountability and faster decision making

$200K
Project cost savings

Delivering a fast, compliant solution

Time was everything for Somnera. For McCarthy, working with Galen Data provided peace of mind knowing one partner could meet their submission deadlines which increased the odds of getting their device to market sooner, "Separately contracting with a software developer, a cloud developer, and a regulatory consulting company would have set us back months or even years." The successful completion of the SleepBridge App and Cloud project was a critical milestone for the Somnera™ System, which also achieved the fastest De Novo clearance ever processed by the FDA for a sleep device.

Galen Data, Inc. provides a turnkey cloud solution for medical device makers that is configurable, secure, and compliant. The company was founded to make device-to-cloud connectivity possible in a matter of weeks instead of months, and at a fraction of the cost. The Galen Cloud™ collects and securely stores data, and includes tools to visualize and analyze that data. Dashboards and alerts for the manufacturer, medical team, and patients are also provided within the platform. The software platform is compliant to FDA, HIPAA, and CE Mark standards, and is ISO 13485:2016 certified. Dozens of companies have partnered with Galen Data to solve their medical device connectivity needs.

Contact us for more information on how Galen Data can quickly get your medical device connected to the cloud.

🌐 **www.GalenData.com**

✉ **hello@galendata.com**

📱 **346-301-0399**