



GraniteLock™ For Medical Devices

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Executive Summary

Advances in technology and manufacturing along with Globalization have created enormous business opportunities within the medical device industry. Commensurate with these opportunities are challenges in regulatory compliance, ensuring proper use of equipment, ensuring all components and products are authentic and assuring revenue.

GraniteKey offers, through its GraniteLock™ line of products, solutions for the medical community to address these challenges:

- Limiting use of disposable peripheral devices - such as catheters, patient interface devices for safety, revenue assurance, and allowing for new business models
- Peripheral authentication - to ensure peripherals (electronic or non-electronic) are authentic
- Intellectual Property (IP) Protection
- Anti-cloning - ensuring products or electronics are authentic
- Anti-tampering and Asset Tracking
- Secure remote updates of firmware for configuration management
- Threat modeling and risk analysis to address regulatory issues

Given the large investment to bring a medical device or product to market, it is important to consider the approaches you can take to protect this investment, early in the product lifecycle.

Previous Options

Organizations have been formulating ways to protect their business models since time immemorial. For many years, cartographers have protected their maps through the clever insertion of false streets, and were quick to challenge anyone who counterfeited their

work. As time progressed, methods for protecting business models began to rely on legal protection of intellectual property, coupled with methods such as controlling the supply chain of materials and components, and the development of proprietary complex designs.

Today, device manufacturers are facing deterioration in the effectiveness of these methods of protection due to Globalization, cost pressures and Patent Reform.

Globalization has benefited manufacturers in terms of reducing their costs for materials and designs, but has also increased their risk. The speed at which designs can be duplicated and mass manufactured is staggering. Furthermore, cost reduction pressures in the industry have increased the incentive for medical practitioners to violate use restrictions on devices which increases risk of liability as well as revenue losses for the manufacturer. Finally, Patent Reform has created an environment which will deliver a significant blow to medical device manufacturers as they attempt to seek remediation for IP violations.

Medical device manufacturers who rely on business models based on the revenue for single or limited-use disposable devices are particularly vulnerable to the difficulty in enforcing and sustaining such a model, both from the perspective of preventing the customer from violating the usage agreement, and in

attempting to prevent a black market from producing counterfeits.

GraniteKey Solutions

GraniteKey specializes in delivering Secure Solutions™ through our Solid Foundations™ process. We first look at the business objectives and processes of our clients and create a threat model and risk analysis to determine which of our GraniteLock™ product configurations addresses your needs:

GraniteLock™ Peripheral Authentication and Limiting Use

Devices which require the enforcement of single or limited use of peripherals which are connected to a base unit are commonly used to ensure quality and cleanliness. Most recently this model is being increasingly used to create innovative business models which shift more of the cost/revenue to a variable cost (per patient) model which helps device manufacturers to compete in an increasingly cost sensitive medical market.

In addition to enforcing limited use, the same technology can be used to ensure the device is authentic. One of our customers had lost a significant amount of revenue due to not only the difficulty of enforcing the single use model, but cloning of the device. We were able to provide a solution which prevented further infringement.

GraniteLock™ Anti-Cloning and IP Protection

Your IP may comprise specialized hardware, software/firmware or both. GraniteLock can be used to secure your software against illegal use (e.g. use without a license, feature

enforcement, use on somebody else's hardware), and in some cases against reverse engineering. GraniteLock can also be used to ensure that your hardware will only work with other components that contain your hardware or software.

The use of GraniteLock also allows your IP Protection to fall under the DMCA which increases significantly your legal avenue to remediation. This is especially important given the reduced effectiveness in patent protection resulting from Patent Reform.

GraniteGuard™ Anti-Tampering and Asset Tracking

This solution leverages the technological advancements which have been made in the RFID (Radio Frequency Identification) industry. RFID, which was initially intended as a means of tracking assets, has grown into a field which offers solutions to problems which were previously impossible or economically prohibitive. With the advent of secure RFID technologies, GraniteKey can now offer solutions which can allow device manufacturers to determine if a device has been tampered with without having to open the device, disable the electronics of a device that has been tampered with, and securely track and store sensitive information on a device. GraniteKey has partnered with leaders in the RFID and can provide secure RFID solutions which are custom tailored

to your business needs. GraniteKey was also a founding member of the RFID Security Alliance.

GraniteFlash™ Secure Update

The use of software in medical devices has created nearly unlimited opportunities to make product improvements without having to spend enormous amounts of time and money on engineering, particularly when it comes to hardware. Updating firmware on medical devices saves both time and money, yet this too can be very time consuming and expensive. If you need to send a representative to the field to install an update, or if the customer needs to send the device or devices back to your organization for updates, the cost for configuration updates can be enormous. Through the use of GraniteFlash™ technology, GraniteKey can provide your device with the capability to receive these configuration changes over a secure network connection, or through the use of a secure GraniteKey™ USB token. By leveraging the secure environments available through Trusted Platform Module (TPM), Smartcard, and Board ID (BID) technologies, you can update your devices securely and efficiently at a fraction of the time and costs of traditional methods.

How Does It Work?

GraniteLock™ uses inexpensive cryptographic security modules which contain certificates issued by the GraniteLock™ Licensing Authority. These modules cannot be duplicated or tampered with. These certificates establish authenticity and can also contain rules such as limited use. These modules authenticate each other. In the simple example below,

GRANITEKEY

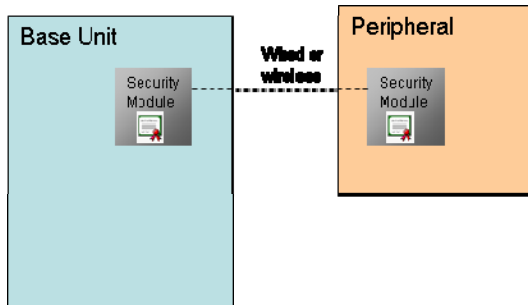
Solid Foundations | Secure Solutions™

the security module in the base unit authenticates the module in the peripheral. Modules can also be used to authenticate different components of the system and can also be used to secure data and software. Please contact us for more information on configurations to fit your needs.

Example

Peripheral authentication and limiting use

Licensing Authority



GraniteKey works with partners who provide us with the secure hardware technologies that enable us to deliver this to our clients. These hardware components come with a variety of features (e.g. wired or wireless, varying levels of security vs. price). The GraniteLock technology is deployed onto these hardware platforms.

Summary

Our primary objective is to ensure that you are provided with the best security technology and techniques

to fit your needs. It is critical to begin with a thorough understanding of your business objectives and processes through the application of our Solid Foundations™ approach. The technological needs fall out of this process. This common sense approach has lead to delighted clients and rock solid solutions.

Please take the next step and contact us for an initial consultation, and let us help you achieve maximum business results.

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