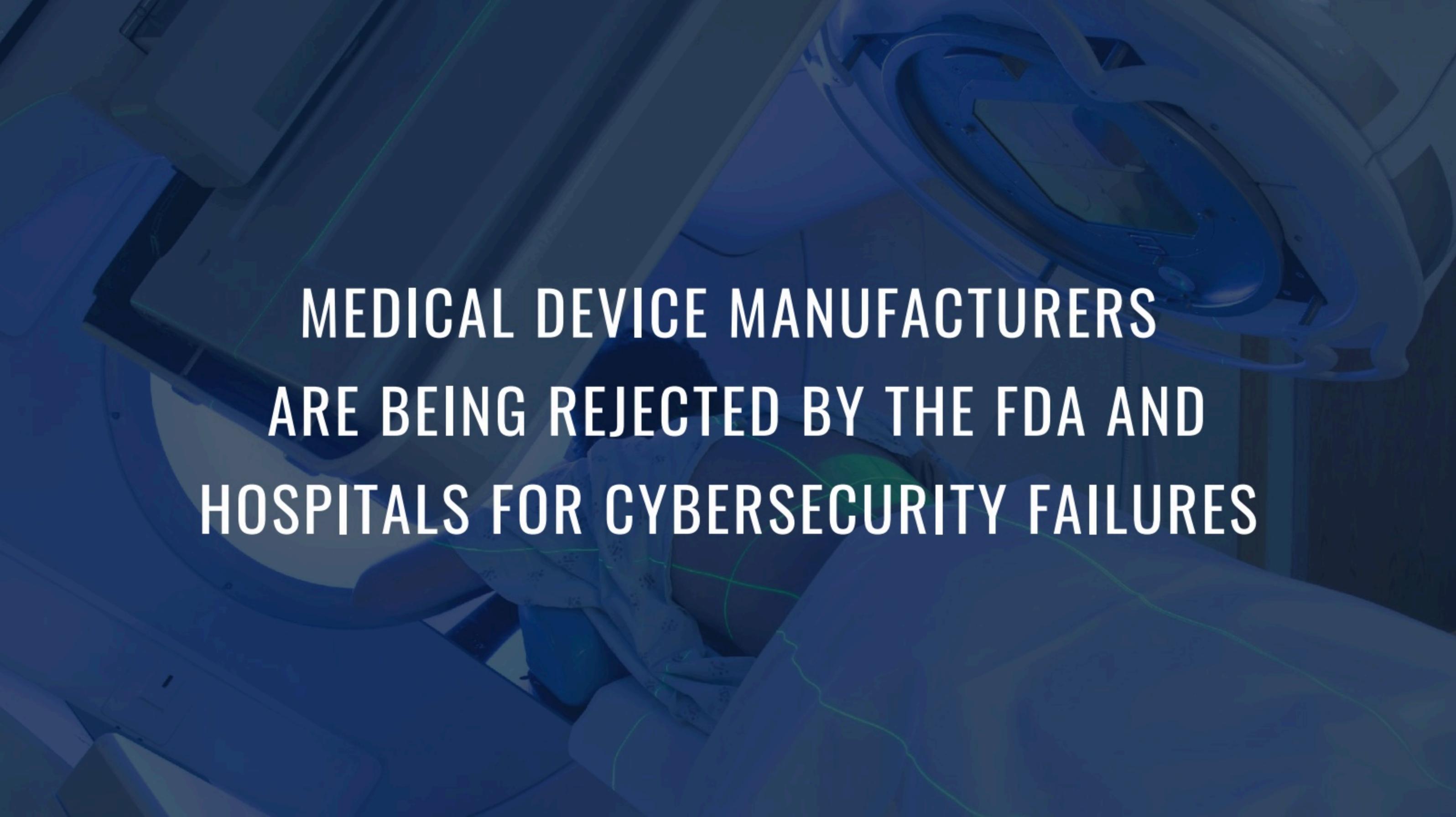




medcrypt

HELPS MEDICAL DEVICE MANUFACTURERS BUILD DEVICES THAT ARE SECURE BY DESIGN



**MEDICAL DEVICE MANUFACTURERS
ARE BEING REJECTED BY THE FDA AND
HOSPITALS FOR CYBERSECURITY FAILURES**

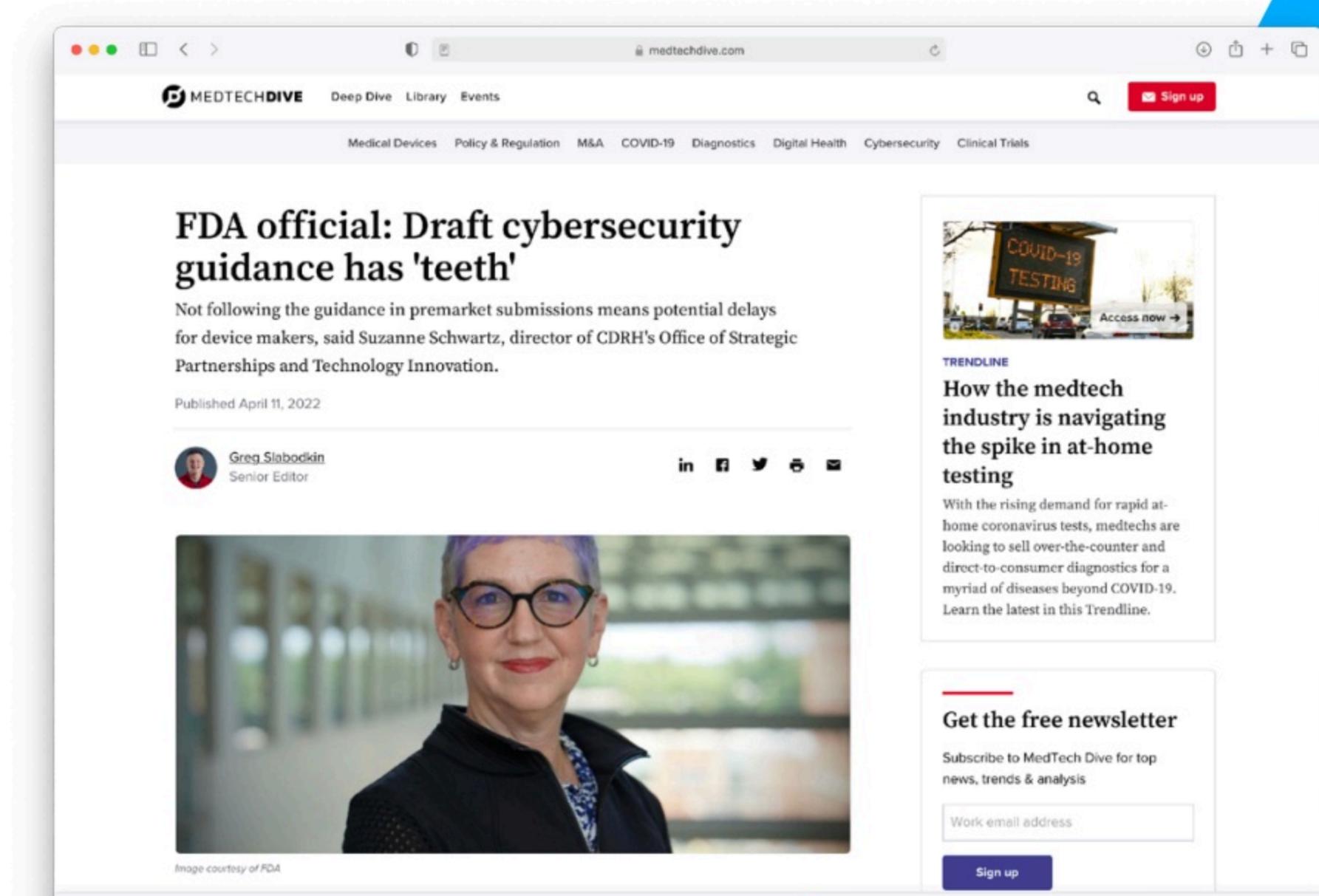
THE COMMON DENOMINATOR AMONG THESE MODALITIES: CYBERSECURITY-DRIVEN RECALLS

Total MDM Market	\$521B
Diagnostic Imaging	\$94B
Patient Monitoring	\$37B
Anesthesia / Respiratory	\$34B
Diabetes	\$19B
Radiation Oncology	\$6.8B
Drug Infusion	\$5B
Neurostimulation	\$4.5B
CRM	\$4.4B
Surgical robotics	\$3.6B

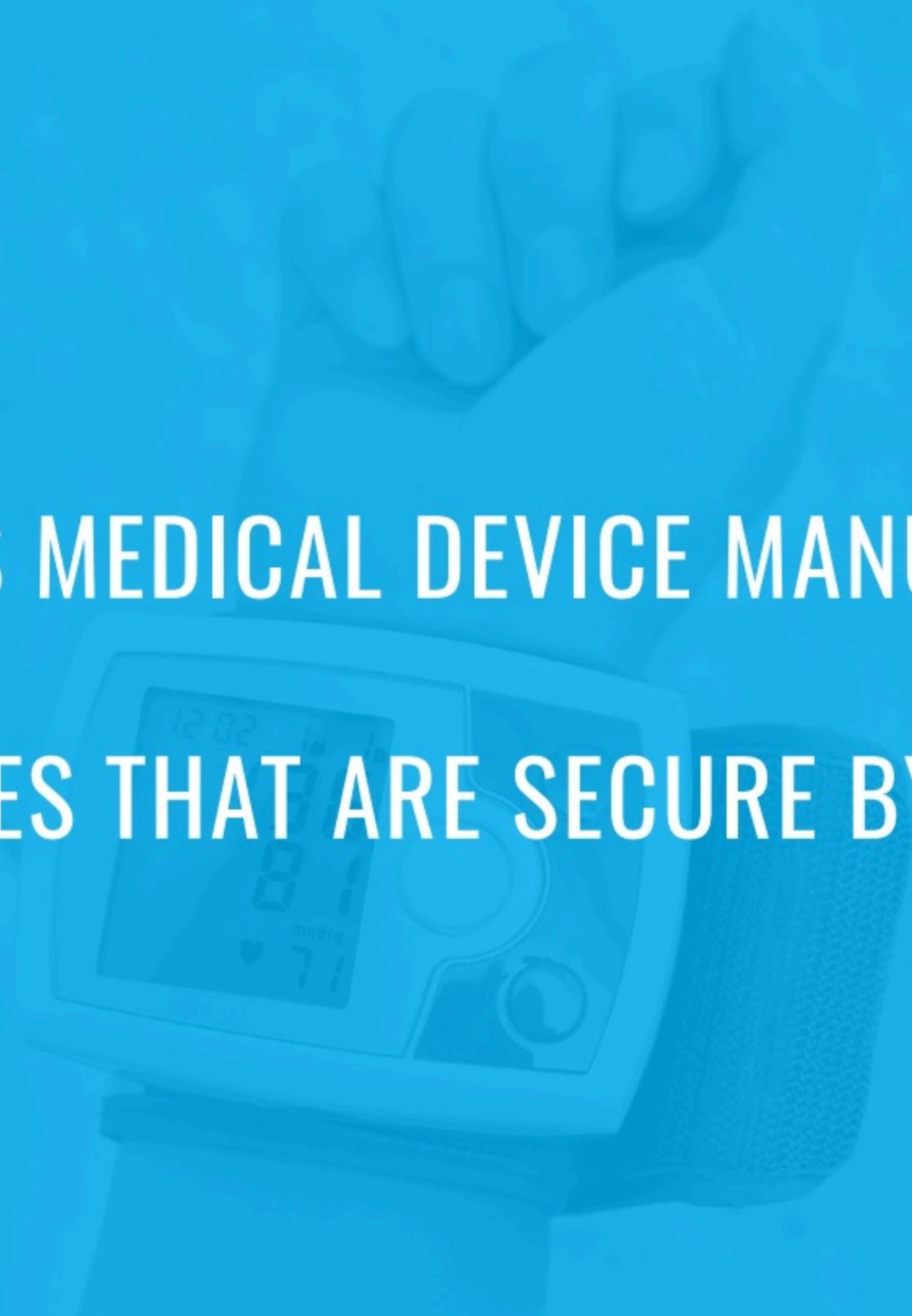
DEVICE MANUFACTURERS NEED TO SECURE \$1T OF NEW AND LEGACY MEDICAL DEVICES IN THE NEXT 3 YEARS

APRIL 7, 2022: THE FDA'S MUST-HAVE FEATURES

-  Secure by Design
-  Cryptographic Signatures
-  Device Monitoring
-  Vulnerability Management



The screenshot shows a web browser displaying an article on the MedTech Dive website. The article title is "FDA official: Draft cybersecurity guidance has 'teeth'". The sub-headline reads: "Not following the guidance in premarket submissions means potential delays for device makers, said Suzanne Schwartz, director of CDRH's Office of Strategic Partnerships and Technology Innovation." The article was published on April 11, 2022, and is written by Greg Slabodkin, Senior Editor. Below the text is a photograph of Suzanne Schwartz. To the right of the article is a "TRENDLINE" section titled "How the medtech industry is navigating the spike in at-home testing", which includes a small image of a COVID-19 testing sign and a "Sign up" button for a free newsletter.

A hand wearing a smartwatch with a digital display showing time and heart rate. The watch face displays '12:02' at the top, a large '81' in the center, and '71' at the bottom. The background is a solid blue color with a faint, semi-transparent image of the hand and watch.

**MEDCRYPT ALLOWS MEDICAL DEVICE MANUFACTURERS
TO BUILD DEVICES THAT ARE SECURE BY DESIGN.**



Vulnerability Tracking

HEIMDALL

- Generates SBOM
- Supports multiple formats
- Monitors vulnerability per SBOM version
- Tracks dependencies across device platforms
- Identifies vulnerabilities and affected devices
- Forensically links vulnerabilities & device events
- Works on new, existing, and embedded devices

The screenshot shows the HEIMDALL web interface. The browser address bar displays 'heimdall.demo.medcrypt.co'. The page title is 'medcrypt' and the user is logged in as 'Ravenclaw'. The interface includes a sidebar with 'Vulnerabilities', 'Products', and 'Allas'. The main content area is titled 'HEIMDALL' and features a filter section with 'Products' (Ravenclaw's Diadem), 'Versions' (1.1.0), and 'Source' (NVD). Below the filters is a table of vulnerabilities.

Product	Version	Dep Name	Dep Supplier	Dep Version	Vulnerability ID	Severity	Modified	Product Impact
Ravenclaw's Diadem	1.1.0	zeromq	zeromq	4.1.4	CVE-2021-20236	v2 7.5 v3 9.8	06/02/21	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2023-11635	v2 5.0 v3 7.5	04/08/22	NONE
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2023-11626	v2 7.5 v3 9.8	04/08/22	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2023-13434	v2 2.1 v3 5.5	06/14/21	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2023-13435	v2 2.1 v3 5.5	06/14/21	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2023-13620	v2 4.4 v3 7.9	03/10/22	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2023-13631	v2 2.1 v3 5.5	03/10/22	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2023-13632	v2 2.1 v3 5.5	03/10/22	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2023-15358	v2 2.1 v3 5.5	03/10/22	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2019-19645	v2 2.1 v3 5.5	03/10/22	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2019-19646	v2 7.5 v3 9.8	03/10/22	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2018-20346	v2 6.8 v3 8.1	07/31/21	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2018-20505	v2 5.0 v3 7.5	06/19/19	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2018-20506	v2 6.8 v3 8.1	07/31/21	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2018-6740	v2 5.0 v3 7.5	06/29/21	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2017-10989	v2 7.5 v3 9.8	10/03/19	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2015-6153	v2 4.4 v3 5.9	10/30/18	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2015-3414	v2 7.5	07/19/18	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2015-3415	v2 7.5	07/19/18	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2015-3416	v2 7.5	07/19/18	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2015-3712	v2 7.5	11/20/20	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2015-5895	v2 10.0	12/22/16	UNKNOWN
Ravenclaw's Diadem	1.1.0	sqlite	sqlite	3.0	CVE-2015-6862	v2 6.6	03/25/17	UNKNOWN
Ravenclaw's Diadem	1.1.0	openssl	openssl	1.1.1g	CVE-2023-1971	v2 4.3 v3 5.9	04/06/22	UNKNOWN
Ravenclaw's Diadem	1.1.0	openssl	openssl	1.1.1g	CVE-2021-23820	v2 5.0 v3 7.5	04/04/22	UNKNOWN

Displaying 33 of 33

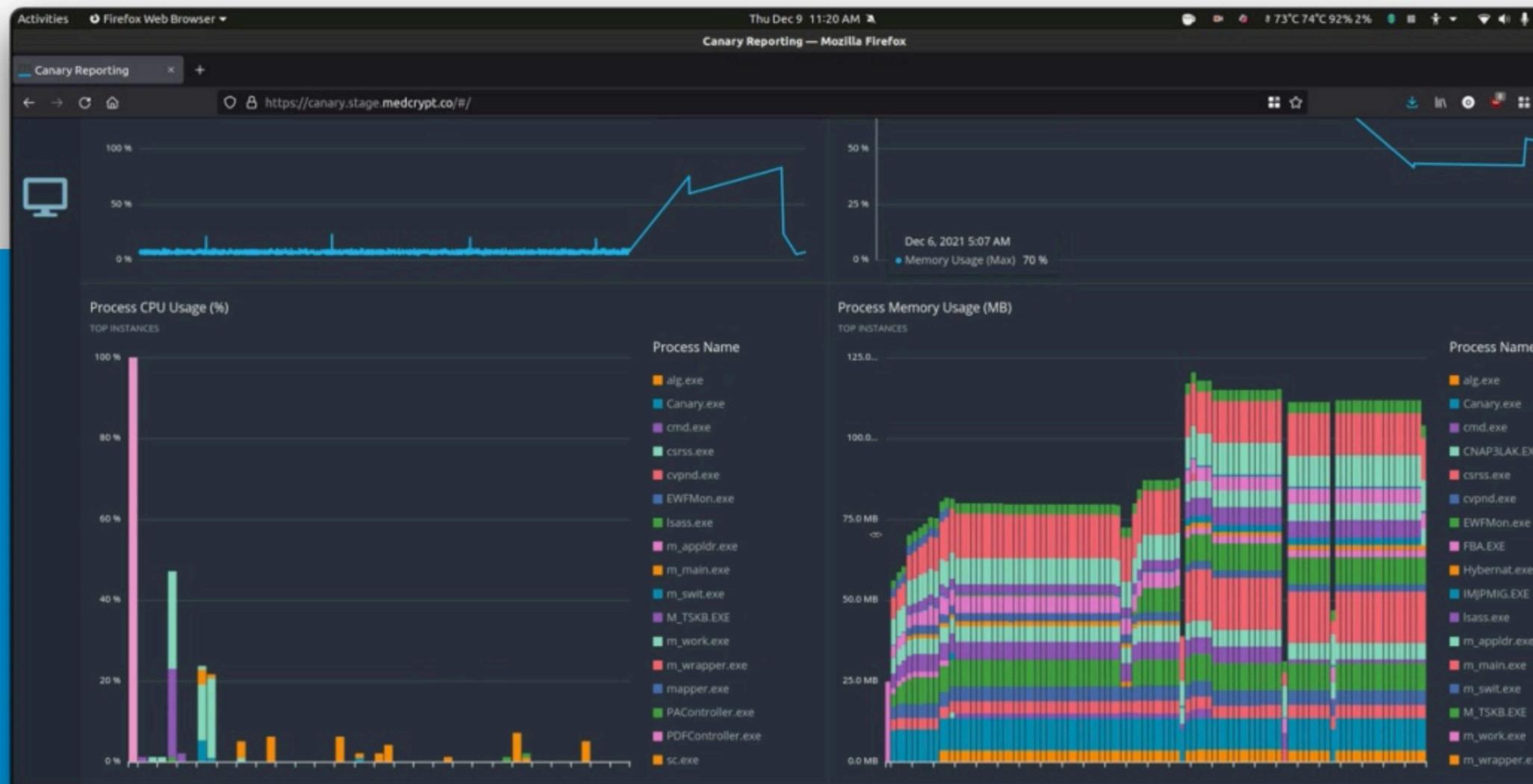
Export Vulnerabilities



Behavior Monitoring

CANARY

- Enables postmarket monitoring
- Captures security event data and device *metadata*
- Analyzes and alerts
- Supports intermittent connectivity
- Determines if a vulnerability is being exploited
- Works on new, existing, and embedded devices





Cryptography

GUARDIAN

- Easy to use API
- Proven Crypto
- Unique device key pairs
- Customizable certificate management
- Wide platform support
- Works on new, existing, and embedded devices

```
/* finding channel in system */
medcrypt::Coordinates coordinates = {"MyServiceName", "BaseSession", "MyChannelName"};
medcrypt::ChannelGuard* my_channel;
status = my_guardian->FindChannelGuard(coordinates, my_channel);

/* sending data */
std::string tx_buffer = "my data goes here";
my_channel->DataForChannel(tx_buffer);
my_guardian.Run();

/* receiveing data */
std::string rx_buffer;
my_guardian.Run();
my_channel->DataFromChannel(&rx_buffer);
```



Med Device Information Sharing Organization

- FDA incentivizes ISAO membership
- MedISAO is the only MDM-focused ISAO
- Provides MedCrypt tremendous sales pipeline

MEDISAO

MEDICAL DEVICE CYBERSECURITY

MedISAO is an organization, composed of members of the medical device community, that is dedicated to improving the security of medical devices through education, awareness and advocacy.

MedISAO provides cybersecurity information sharing, education and tools tailor-made for the medical device industry.

MedISAO is a registered ISAO with an FDA MOU providing compliance with the FDA's recommendation in the Postmarket Management of Cybersecurity in Medical Devices.

INFORMATION SHARING AND ANALYSIS FOR THE MEDICAL DEVICE COMMUNITY

From the FDA's Guidance on Postmarket Management of Cybersecurity in Medical Devices:

"The Agency considers voluntary participation in an ISAO a critical component of a medical device manufacturer's comprehensive proactive approach to management of postmarket cybersecurity threats and vulnerabilities and a significant step towards assuring the ongoing safety and effectiveness of marketed medical devices..."

WHY SHOULD I JOIN MEDISAO?

TEAM HIGHLIGHTS



MIKE KIJEWSKI
FOUNDER OF GAMMA BASICS,
SOLD TO VARIAN



ERIC PANCOAST
FOUNDER OF GAMMA BASICS,
SOLD TO VARIAN



VIDYA MURTHY
FMR BECTON DICKINSON
CYBERSECURITY



SETH CARMODY
FMR FDA CYBERSECURITY
LEAD



AXEL WIRTH
FMR SYMANTEC HEALTHCARE
LEAD



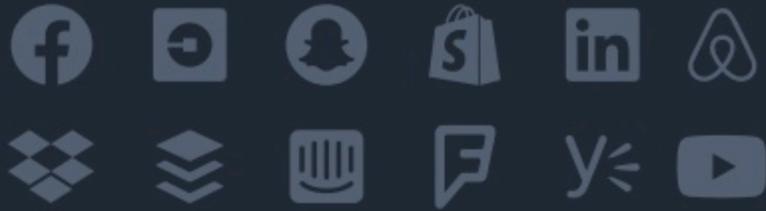
SHANNON LANTZY
FMR BOOZ ALLEN HAMILTON

SUMMARY

- NEW FDA CYBERSECURITY RULES RELEASED APRIL 2022
- MEDCRYPT'S TOOLS HELP MED DEVICE MANUFACTURERS BUILD PRODUCTS THAT ARE SECURE BY DESIGN, AVOIDING RECALL & REGULATORY/ CUSTOMER REJECTION
- 55 CUSTOMERS, INCLUDING 3 OF THE TOP 5 MDMS
- TEAM INCLUDES FORMER FDA, SYMANTEC, MEDTRONIC, BECTON DICKINSON, VARIAN, LOCKHEED, AND BOEING
- RAISED \$14M TO DATE FROM SECTION 32, JOHNSON & JOHNSON, Y COMBINATOR, ENIAC, AND OTHERS



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