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US Regulatory Roundup, April 2021: Medical Software, FDA Remote Reg Assessments, Medtronic Recalls, And More

by Shawn M. Schmitt

An FDA rule that says the agency will no longer regulate eight different types of medical software, an explainer of the FDA's Remote Regulatory Assessments, high-risk class I recalls for medtech giant Medtronic, and more topped our list of most-read *Medtech Insight* articles in April.

Rule Says FDA Won't Regulate 8 Software Types

If you're the maker of any of eight different types of medical software, then you can breathe easy: A final rule from the US Food and Drug Administration that went into effect in mid-April says the agency won't regulate the programs anymore because they're not devices in the eyes of the FDA.

Our reporting on the new rule was of most interest to *Medtech Insight* readers in April.

Here are the eight software types and product codes covered by the rule:

- Calculator/Data Processing Module for Clinical Use (JQP, NVV)
- Continuous Glucose Monitor Secondary Display (PJT, PKU)
- Automated Indirect Immunofluorescence Microscope and Software-Assisted System (PIV)
- Medical Device Data System (OUG)
- Home Uterine Activity Monitor (LQK, MOH)

- Medical Image Storage Device (LMB, NFF)
- Medical Image Communications Device (NFG, LMD)
- Picture Archiving and Communications System (QIH, OMJ, NWE,PGY, OEB, QKB, PZO, NFJ, LLZ)

Firms should be aware, however, that the provision "excludes software functions that are solely intended to transfer, store, convert formats or display, unless such functions are intended to interpret or analyze clinical laboratory test or other device data, results and findings," the rule says. "This includes functions that are intended for data retrieval, receipt or transmission."

FDA Remote Regulatory Assessments: An Explainer

Meanwhile, our *No. 5 story* from April gave device makers an inside look at how the FDA's Remote Regulatory Assessments will unfold. While not an official agency inspection, an RRA is a type of desk audit that has taken the place of routine in-person facility inspections as the pandemic continues.

In a three-page explainer sent to a Florida device firm and obtained by *Medtech Insight*, the FDA details a company's role during an assessment, including best practices for transferring electronic files to the agency. The document also specifies who to contact if the firm has problems with an investigator, among other instructions and explanations.

The FDA does not say it will use video – recorded or live – during an RRA, despite the agency's earlier interest in exploring video's use during virtual assessments. The FDA's apparent decision to not use video could be due to industry's longtime aversion to investigators taking photographs during inspections.

Interestingly, an investigator's RRA report is not given to a device maker unless it requests a copy through the *Freedom of Information Act*.

And in last month's *No. 8 story*, Elizabeth Miller, assistant commissioner for medical products and tobacco operations within the FDA's Office of Regulatory Affairs, conceded that "firms may decline to participate in these Remote Regulatory Assessments," but she quickly followed that up with a thinly veiled warning, noting that "FDA management will determine if a more immediate on-site inspection is needed" for companies that refuse an RRA.

Rough Times For Medtronic's HeartWare Device

April wasn't kind to *Medtronic PLC*, with four of the medtech giant's recalls being designated as high-risk class I by the FDA. Our reporting on one of those class I's – a recall of the firm's

HeartWare Ventricular Assist Device (HVAD) – was our *No. 4 story* from last month.

In that case, there is a "risk of wear and tear of the connector plugs (power sources, data cable, and alarm adapter), which could cause damage to the controller port metal pins," the agency said in mid-April, noting that "damaged controller ports may prevent power cables and data cables from being connected to the controller and lead to a full or partial stop of the pump." The FDA said 12 deaths and eight serious injuries were reported.

That recall was HeartWare's second class I action in the span of roughly six weeks. On 1 March the FDA gave the high-risk designation to a *recall of HVAD Pump Implant Kits*. The agency said at the time that the kits could cause the HeartWare device to "fail to initially start, restart or have a delay in restarting after the pump was stopped."

News of Medtronic's other class I recalls from April can be found *here*, *here* and *here*.

Did Pandemic Shift FDA's Thinking Around At-Home Diagnostics?

The FDA and industry have long sought to bring diagnostic testing closer to patients in the home setting, in a way that can be done rapidly and is reproducible – but the agency has been concerned that people didn't have a good way to collect an appropriate sample at home.

Well, the ongoing pandemic may have upended the FDA's thinking around that, as we explained in our *No. 6 story* from April.

"There are very few upsides associated with this pandemic. Let me be very clear with that: There are very, very few upsides coming out of the pandemic," Hogan Lovells partner Randy Prebula told *Medtech Insight*. "But one of the upsides we're aware of is that there's been an opportunity to evaluate some of FDA's underlying assumptions about how samples can be taken, who can take them, and how they can be tested."

When the pandemic started, "everybody wanted a nasopharyngeal swab. Everybody wanted it to come through a health care provider. And everybody wanted a health care provider to be able to walk across the hall to a laboratory so the test could be run. And that's just not conducive to testing hundreds of thousands – or millions – of people in a short period of time for an emerging disease," he said.

Read our case study story *here*, or listen to our *Device Week* podcast on the topic below:

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Other Top Stories

These articles rounded out our Top 10 list in April:

- *No. 2* & *No. 3* stories: Our coverage of the departure of the FDA's second-in-command, Amy Abernethy, was of high interest to readers. She left the agency on 23 April after a two-year stint as principal deputy commissioner. In an *exit interview* with *Medtech Insight*, Abernethy discussed her future and explained why now was the right time to leave the job.

- *No. 7 story*: Two top officials in the FDA's Center for Devices and Radiological Health warned of delays in the agency's review of submissions for new products that aren't directly tied to the pandemic.

- *No. 9 story*: The FDA sounded the alarm over recent adverse event reports that indicate patient infections linked to reprocessed urological endoscopes, including cystoscopes, ureteroscopes and cystourethroscopes. The scopes are used by health care providers to view and access a patient's urinary tract.

- *No. 10 story*: Regulators in the US and Canada have taken stock of their enforcement activities in the first year of the pandemic, and now they're focused on what's coming next.

The 10 most popular US regulation and policy stories in April, as determined by reader interest, are listed in the table below.

Rank	Story
1	*FDA Will No Longer Regulate Certain Medical Software*
2	*FDA's Outgoing Abernethy: 'I Feel Very Strongly About Janet Woodcock'*
3	*Exit Interview: Abernethy Tells Why She's Leaving FDA – But Staying On Her Own Path*
4	*12 Deaths Prompt Another Class I Recall For Medtronic's HeartWare – The Firm's Fourth In Recent Weeks*
5	*From Electronic Docs To FOIA Requests, FDA Lays Bare Its Process For Remote Regulatory Assessments*
6	*Lucira Health's Unexpected Sprint To A First-Of-Its-Kind EUA From FDA: The Inside Story*
7	*Submitting A Non-COVID-19 Product For FDA Review? Then Take A Seat, It's Gonna Be Awhile*
8	*FDA Presses Domestic Manufacturers To Engage In Remote Regulatory Assessments In Lieu Of Inspections*
9	*'Numerous' Adverse Event Reports Of Infections Spark FDA Warning For Urological Endoscopes*
10	*It's COVID-19 'Clean-Up Time': FDA, Health Canada Hint At What's Next In Enforcement*