



# Association for Pathology Informatics

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## Re: 86 FR 4088 - Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements

March 15, 2021

### To Whom It May Concern:

The Food and Drug Administration's Federal Register (FR) Notice of January 15, 2021, proposes, in part, to exempt 83 class II devices from premarket review as required under section 510(k) of the Food, Drug, and Cosmetic Act. Amongst the product codes listed in Table 6 of the Notice ("Class II Devices and Unclassified Devices Proposed Exempt from 510(k) Requirement") are several that comprise core components of digital pathology systems. As requested in the Notice, the Association for Pathology Informatics (API) herein provides its insights, recommendations, and requests for comment on this proposal.

API is the only national organization dedicated exclusively to the development and practice of pathology informatics. It plays a critical role in enabling and empowering informatics to meaningfully contribute to the provisioning of safe, effective, and efficient patient care. To this end, the API supports both clinical practice and innovation in pathology informatics through research, education, and advocacy. Moreover, the API plays an active role in contemporary legal, ethical, social, and regulatory issues related to pathology informatics. It counts amongst its membership many world leaders in their respective informatics subspecialties. API also maintains and seeks to develop further relationships with other professional societies and industry partners with similar interests and goals.

The Association of Pathology Informatics aligns with the FDA's priorities in risk management, interoperability, and standardization. We fully support the direction behind this FR Notice as it relates to digital pathology devices. More broadly, API supports the FDA's recent efforts to establish a more agile and adaptive regulatory framework that can keep pace with accelerating medical innovation. Within that framework, we seek to provide the FDA with continuous feedback as part of the larger community of early adopters of digital and computational pathology technologies and clinical workflow models.

Before the COVID-19 Public Health Emergency (PHE), regulation of digital pathology devices contributed to the greatly delayed deployment and lower adoption rate in the United States than nations operating under different and much less restrictive regulatory domains (e.g., Canada, the European Union, and Japan). Likewise, this regulatory framework required end-to-end evaluation of Whole Slide Imaging (WSI) systems until recently. This approach meant that each component of the overall image pipeline was tied to monolithic configurational approval. The consequence was the prevention of device substitution, even when new components with superior performance became available.

One result of the pandemic was a pivot toward telemedicine, with pathology being one of the specialties actively seeking to leverage remote diagnostic technologies' benefits. About 6% of pathologists used digital pathology devices for remote diagnosis (i.e., telepathology), which allowed them to facilitate continuity of care while protecting pathologists and laboratory staff's health (*reference: COVID-19 Pathologist Impact Survey: Summary of Findings, October 2020*). This practice model was under many state directives, which stipulated that remote sign-out work is feasible and should be carried out remotely, when possible, to curb the horizontal transmission of SARS-CoV-2.

As of April 2020, in consonance with these COVID-19 PHE protective efforts, the FDA issued its guidance on remote digital pathology devices, which permitted modification to FDA-cleared digital pathology devices and the marketing of non-510(k)-cleared digital pathology devices intended for telepathology. This relaxation of oversight, along with the Centers for Medicare & Medicaid Services (CMS) Memorandum of March 26, 2020, afforded laboratories the autonomy and flexibility to respond to the crisis by assembling digital pathology systems, using carefully-selected:

1. Consumer off-the-shelf (COTS) computer monitors
2. Research use only (RUO) slide scanners
3. Any other interoperable components required for digital pathology sign-out

A valuable byproduct of this forced experiment was a large body of real-world experiential feedback regarding the safe application of digital pathology for patient care and the concurrent accumulation of a wealth of operational knowledge concerning how effectively to use such modular solutions. The attached document is our best attempt to summarize the findings and opinions of our members.

**To briefly summarize API's feedback:** We support continuing FDA oversight to varying degrees for the digital pathology product codes QKQ, PSY, and OEO. By contrast, based on our members' vital feedback, we believe that FDA oversight of the digital pathology product code PZZ (digital pathology display) is no longer required. Detailed comments and recommendations for each of these digital pathology product codes are in the attached document.

Moreover, API's stated position, in this cover letter and the attached document, has the endorsement of four leading pathology organizations:



American Society for  
Clinical Pathology



Association of Directors of  
Anatomic and Surgical Pathology



Association of Pathology Chairs



COLLEGE of AMERICAN  
PATHOLOGISTS

API is thankful for the endorsement of these leading pathology organizations and the opportunity to comment on these specific product code decisions, which are critical to our field's future. More broadly, we are grateful to work with the Department of Health and Human Services to pursue our shared interest and provide the United States citizens with the highest possible healthcare standard.

Sincerely,

A handwritten signature in black ink, reading "S. Joseph Sirintrapun", enclosed within a thin black rectangular border.

S. Joseph Sirintrapun, M.D.

*On behalf of the Association for Pathology Informatics Governing Council*

## **GENERAL COMMENTS**

### **Ramifications of regulation in digital pathology**

The COVID-19 pandemic has introduced digital pathology to many pathologists who may not have otherwise engaged with the technology. Simultaneously, the rapid shift to remote work environments has also exposed limitations in the current regulatory framework. Questions remain regarding the future of digital pathology device regulation and whether current regulatory exemptions will revert or expand. Because of the antiquated pre-COVID-19 regulation of digital pathology devices, there is considerable clinical inertia to revert to traditional practice patterns. The challenge lies in improving the current regulatory framework.

Federal Notice 86 FR 4088 includes components of a digital pathology workflow (product codes PZZ, QKQ, PSY, and OEO). In general, API supports and encourages the easing of regulation for digital pathology devices. However, our understanding is that this FR notice goes beyond just easing regulation and proposed permanent removal of FDA oversight from the class II devices named. While API endorses the PZZ digital pathology product code's permanent removal, it may be premature to permanently deregulate the other digital pathology product codes (QKQ, PSY, and OEO). To this end, the API requests comment on instituting an "accommodative" approach that preserves critical oversight while significantly reducing the overall regulatory burden.

With permanent deregulation of the QKQ, PSY, and OEO digital pathology product codes, come possible downstream burdens for computational pathology. Given the dependence of image analysis and artificial intelligence (AI) applications on these products, after possible removal of permanent oversight of these three digital pathology product codes, it is foreseeable that there could be the potential for undesirable and unintended consequences.

Permanent oversight removal for these three digital pathology product codes may also erode interoperability and standardization. Less interoperability and standardization would likely impede long-term digital pathology development and lead to the inconsistent and non-efficacious deployment of downstream image analysis and AI applications, which are entirely dependent on the consistency and fidelity of these digital image acquisition components. The overall result is the disenfranchisement and disintermediation of pathologists, who could otherwise be better situated to fully leverage digital and computational pathology towards our patients' and professional colleagues' benefit.

### **How device regulation in digital pathology is different from other medical devices and recommendation for engagement partnership with digital pathology-enabled organizations like API**

Regulation in digital pathology is different from other disciplines because of its regulation on two fronts by CMS and the FDA. CMS regulates the validation for the digital pathology devices used in clinical practice through CLIA'88 (42 CFR 493), and the FDA regulates the digital pathology devices themselves, under the medical device rubric. Other medical specialties concern themselves only with the FDA.

For digital pathology, the FDA need not broadly regulate all aspects of a given device, especially given the FDA's limited resource bandwidth. Though well-intentioned, broader FDA regulation has the potential to create an overburden without producing a commensurate increase in device safety. Moreover, because digital pathology regulation with CMS and FDA is intertwined but uncoordinated, total FDA permanent regulatory flexibility has unforeseen consequences with CMS regulations, which are difficult to disentangle for the practicing pathologist.

In contrast, the FDA need not withdraw entirely from regulating digital pathology. Instead, FDA can take a coordinated approach to device regulation that complements CMS's additional layer of oversight which would provide a "middle ground" for moving forward. We propose that the FDA focus on individual devices in a controlled, systematic approach within a tighter scope of monitoring risk, interoperability, and standardization (i.e. manufacturing). CMS would then validate the integration and utilization of digital pathology devices in laboratory testing.

API strives to establish best practices and works with other pathology organizations to navigate the regulatory interplay with the CMS and the FDA required for the pathology practice's digital pathology transformation. CMS and the FDA should lean on API members' collective wisdom, based on our real-world experience in safely translating digital pathology technologies into clinical practice.

#### **Flaws in our risk surveillance with recommendation and request for comment**

Risk surveillance data gets collected from the Manufacturer and User Facility Device Experience (MAUDE) database. MAUDE revealed a lack of non-death-related adverse events the last ten years (including the pandemic to date) for specific Class II devices, specifically the four digital pathology product codes (PZZ, QKQ, PSY, and OEO) identified in the FR Notice. API recognizes that the absence of events contributed to the conclusion that 510(k) premarket notification is no longer necessary to ensure devices' safety and effectiveness under these product codes. However, API is concerned that this absence of reported risk events may not fully reflect the true risk. Thus, it is insufficient to warrant permanent removal of oversight for three (QKQ, PSY, and OEO) of the digital pathology product codes.

While MAUDE is a vital source of information, it remains a "passive surveillance system." Thus MAUDE has limitations, including the potential for incomplete, inaccurate, or biased reporting. MAUDE historically captures risk events and is not geared towards the FDA's efforts about interoperability <sup>(ref 1)</sup> and standardization <sup>(ref 2)</sup>, which is vital for our comments and recommendations specific to three (QKQ, PSY, and OEO) digital pathology products codes.

The existence and purpose of MAUDE are not widely known to the public or even the medical community. Capturing risk events in MAUDE is somewhat challenging in digital pathology, lacking in specificity. For example, take the rare event of a malignant tumor missed or incorrectly classified by a pathologist using a particular combination of devices resulting in sub-optimal treatment or patient harm. How would this adverse event be recorded in MAUDE for reporting to the FDA? How one would trace back a diagnosis and the resulting clinical decision(s) to an individual device is unclear. Would such

a rare event get captured if the observation time frame is too short? Moreover, searching, categorizing, and aggregating surveillance data is highly manual in MAUDE.

Considering MAUDE's obscurity and its limited ability to capture specificity, API recommends publicizing MAUDE more widely and considering a re-design to enhance MAUDE for continually monitoring, particularly for product codes relating now and for the future in digital pathology and computational pathology. A re-designed MAUDE would provide comprehensive and accurate data of risk, interoperability, and standardization issues required for specific Class II medical devices considering 510(k) exemption.

Digital and computational pathology-enabled organizations like API, the DPA (Digital Pathology Association), and the Alliance for Digital Pathology <sup>(ref 3)</sup> can further promote MAUDE's visibility and recruit the expertise to enhance MAUDE's functionality. A re-designed MAUDE becomes the mainstay surveillance tool to capture risk, interoperability, and standardization for a dynamic digital and computational pathology ecosystem. API requests comment on this recommendation.

### **Request for comment about an "accommodative" regulatory framework versus permanent regulatory flexibility**

API would like to reinforce the need for increased regulatory flexibility and advocate for an "accommodative" regulatory framework for the QKQ, PSY, and OEO digital pathology product codes. API recognizes that the permanent removal of regulatory oversight demands a high bar for maintaining the trust of the pathology and broader medical communities and the public. To protect the community and public trust, API further endorses stepwise regulatory relaxation with mechanisms to ensure continual monitoring and "smart" oversight with more waived devices. Our proposal for an "accommodative" regulatory framework also includes coordination of regulatory oversight between CMS and FDA, with clear delineation of responsibilities and partnerships with organizations like API, DPA, and the Alliance for Digital Pathology <sup>(ref 3)</sup>.

API proposes this "accommodative" regulatory framework as a thoughtful and adaptive approach to regulatory flexibility because it enables "continuous learning" and iteration. An enhanced MAUDE would provide continual technical and manufacturing feedback and is central to this framework. It makes feasible stepwise regulatory openings with close monitoring during periods of regulatory relaxation <sup>(ref 4)</sup>. Clinical evaluation is then up to the pathologists and laboratories who use the systems.

Our proposed "accommodative" regulatory framework thus aligns closely with the way CMS regulates the validation for the instruments used in clinical practice and with the "FDASIA Health IT Report." The latter report recommends "local" accountability (rather than "national regulation") through a local control system or accreditation to address local configuration, implementation, and training of end-users. We believe that our "accommodative" regulatory framework overcomes the overburdening pre-COVID-19 regulatory hurdles by opening stepwise with close monitoring while providing incentives to attract community use, industry innovation to gain widespread acceptance of digital pathology. API requests for comment on an "accommodative" regulatory framework versus permanent regulatory



flexibility for devices now and in the future that do not meet the threshold for permanent regulatory flexibility.

**Comments and Recommendations Specific to These Four Digital Pathology Product Codes identified in the FR Notice.**

**1. PZZ – Digital Pathology Display (21 CFR 864.3700)**

API recommends that digital pathology displays are not FDA-regulated as medical devices and endorses the permanent regulatory flexibility on devices under this product code.

FDA regulates digital pathology devices. However, this is not necessary for digital pathology displays. Required instead are high-quality digital pathology display products that meet minimum specifications to produce an accurate pathology diagnosis. There is enough evidence that digital pathology displays, with enough resolution, will provide accurate diagnoses.

Evidence shows having a display used in an FDA-cleared system is not necessary. Non-medical-grade (i.e., non-FDA-cleared), high-quality monitors (including COTS monitors) that a clinical laboratory deems safe can be used to perform pathologic diagnoses <sup>(ref 5,6,7)</sup>. In some instances, COTS monitors outperformed medical-grade monitors by a significant margin <sup>(ref 7)</sup>. During the peak of the COVID-19 surge, Memorial Sloan Kettering Cancer Center (MSKCC) in New York City performed digital pathology primary diagnosis (sign-out) safely and efficaciously in a remote setting at scale using a wide variety of displays. Digital pathology displays ranged from consumer-grade laptop computers to higher specification desktop computers with high definition dual monitors, none of which were medical-grade <sup>(ref 8)</sup>.

CMS and their respective accreditation bodies (e.g., College of American Pathologists [CAP] and The Joint Commission) regulate clinical laboratories and handle digital pathology displays as an integrated digital pathology practice component through 42 CFR 493. These accreditation bodies can verify or validate the digital pathology systems used for clinical diagnosis. Not required are devices used within these systems that are FDA-cleared. Clinical laboratories and individual pathologists have the expertise to determine if a monitor has sufficient resolution and is safe to make accurate diagnoses and determine which commercial grade products to use in medical practice, regardless of whether the monitor is an FDA-cleared device. In current practice, pathologists have already made such local decisions regarding the optical quality of microscopes and microscope lenses and the suitability of histologic preparations for making diagnoses.

Opening up the FDA's regulation on digital pathology displays creates innovative opportunities to investigate mobile devices' feasibility and enable remote digital diagnosis without obtaining medical-grade devices. CMS can then address deficiencies in digital pathology display for digital pathology practice through their existing regulatory mechanisms rather than FDA.

Lastly, digital pathology displays engage only human vision, which is more resilient to image artifacts and noise, over computer vision. Therefore, there are NO foreseeable dependencies for

image analysis and artificial intelligence (AI) applications on digital pathology displays. For this reason, the API predicts that the permanent removal of regulatory oversight for digital pathology displays would not produce undesirable and unintended downstream consequences for computational pathology.

2. **QKQ – Digital Pathology Image Viewing and Management Software (21 CFR 864.3700)**

API recommends that Digital Pathology Image Viewing and Management Software are not FDA-regulated as medical devices evaluated for risk, BUT rather as medical devices evaluated to ensure interoperability and standardization through an "accommodative" regulatory framework. API also requests comment.

Digital pathology image viewing and management software are components in the "pixel pipeline" of digital pathology systems. In radiology and other imaging disciplines outside of pathology, similar image viewing and management software get referred to as "medical device data systems" <sup>(ref 9)</sup>. In radiology, these systems exist as class I devices, so long as they do not modify the pixels <sup>(ref 10,11)</sup>. There is enough evidence to show a low risk of using digital pathology image viewing and management software components under this product code, justifying the argument for not regulating these components for risk. Moreover, for digital pathology, the accountability for risk is on clinical laboratories. Individual pathologists have the expertise to verify and validate such components are safe to make accurate diagnoses and determine which commercial-grade products to use in medical practice. Therefore, such components and their risk performance align more under CMS, regulating the validation for the instruments used in clinical practice versus the FDA.

Excluding risk evaluation, continual evaluation for interoperability and standardization is our proposed approach to FDA regulatory oversight. For components defined as "medical device data systems" <sup>(ref 9)</sup>, the evaluation for interoperability and standardization is not currently present. Like other pathology organizations (i.e., DPA), API advocates a modularized approach to digital pathology system components that enable interoperability and standardization. Continual oversight for interoperability and standardization for components under QKQ will enable the standardized, safe, and efficacious deployment of image analysis and AI applications dependent on QKQ components. Having interoperability and standardization structured within these components through an "accommodative" regulatory framework will promote innovation and access for new platforms and applications to ensure a robust market for an enabled digital and computational ecosystem.

3. **PSY – Whole Slide Imaging System (21 CFR 864.3700)**

API does NOT endorse the permanent regulatory flexibility, particularly for specific components under the PSY (Whole Slide Imaging System) product code that do not fall under the PZZ and QKQ product codes. Instead, API recommends the creation of a new product code for non-PZZ and QKQ components. For components under that new product code, API recommends approaching opening systematically and in partnership with digital and computational pathology-enabled organizations like API, DPA, and the Alliance for Digital Pathology <sup>(ref 3)</sup>. Such



components need evaluation for risk and to ensure interoperability and standardization. Likewise, such evaluations get best aligned through an "accommodative" regulatory framework. API also requests comment.

The WSI system includes hardware and software components encompassing digital scanners, digital pathology displays, digital pathology image viewing, and management software. Except for digital scanners, the latter three components fall under PZZ (digital pathology display) and QKQ (digital pathology image viewing and management software) product codes, with regulation targeted according to those product codes. PZZ and QKQ components' broad inclusion under PSY creates confusion, warranting a new, independent product code for the remaining PSY component -- digital slide scanners.

Clearance for PSY devices is relatively recent (2017 and 2019), resulting in limited market history. However, due to MAUDE's biases, the absence of adverse risk events potentially reflects recent market entry and possibly a misrepresentation of safety. One issue noted in a MAUDE report that deserves more scrutiny is tissue detection. Due to the focusing point engineering of digital scanners, there is potential to miss the scanning of highly fragmented tissues and "out of focus plane" cells. Hence, digital scanning on "wet" (cytologic and hematologic) specimens are yet not FDA-cleared or widespread in clinical practice for diagnoses. The sparse use of digital scanning for "wet" specimens leads to scant MAUDE reporting. Our proposed "accommodative" regulatory framework will capture risk events with growing use and accumulated experience over time.

Permanent regulatory flexibility leads to reduced interoperability and standardization long-term. Lack of interoperability locks users to end-to-end vendors with high costs to switch and few opportunities to swap less expensive interoperable components. Radiology suffers from a lack of interoperability with "medical device data systems" <sup>(ref 9)</sup>, "but this is avertable in digital pathology if FDA oversight factors interoperability and standardization.

A consideration for digital scanner evaluation is the inclusion of their corresponding digital image outputs. Besides concerns from permanent flexibility of regulatory oversight for risk, API foresees detrimental computational pathology consequences without oversight for interoperability and standardization of digital scanners (and their digital image outputs). In addition to other components under QKQ, digital scanners (and their corresponding digital image outputs) should allow for the standardized safe and efficacious deployment of image analysis and AI applications, regardless of output specific to the digital scanner. Unlike human vision, computer vision applications are often susceptible to artifacts and noise, image pixel data, and image reproduction (color, contrast, texture, etc.), varying from scanner to scanner.

Interoperability of the different digital and computational pathology components is feasible only with interoperable and standardized data exchange interfaces. To enable interoperability and standardization in this context involves reaching a consensus regarding a standard file format and communication protocol for storage and transmission of images and related information,

then evaluating how closely devices adhere. Having interoperability and standardization, structured within digital scanners through our "accommodative" regulatory framework, will promote innovation expansion and access for new platforms and applications to ensure a robust market for an enabled digital and computational ecosystem.

4. **OEO – Automated Digital Image Manual Interpretation Microscope (21 CFR 864.1860)**

API does NOT endorse the permanent regulatory flexibility. Instead, API recommends approaching opening systematically and in partnership with digital and computational pathology-enabled organizations like API, DPA, and the Alliance for Digital Pathology<sup>(ref 3)</sup>. Such software devices need evaluation for risk and to ensure interoperability and standardization. Likewise, such evaluations get best aligned through an "accommodative" regulatory framework. API also requests comment.

The OEO product code describes software devices that aid in the interpretation of immunohistochemistry (IHC). API acknowledges the clearance of several software devices ("good actors") under this product code over a decade of safe market use. API also believes that MAUDE reporting is proprietary to the software device and not extensible to other software devices. Therefore API is uneasy about endorsing permanent regulatory flexibility for all software devices under the OEO product code. Likewise, there are no disincentives for "bad actors" to enter and integrate into the current pool of "good actors."

Furthermore, API believes there is the extensibility of OEO for AI applications as medical devices (SaMDs), which aid in quantitative interpretation of novel biomarkers and qualitative companion diagnostics. AI SaMDs are rapidly expanding, and the technical understanding around these types of algorithms is still a "black box," requiring more scrutiny when applied to the clinical setting.

Like the FDA, API does endorse a tailored regulatory oversight with the minimal threshold for safety and monitoring of risk events not to overburden innovation and market expansion of promising software devices<sup>(ref 12)</sup>. API also believes that a robust AI SaMDs market relies on interoperability and standardization. Similarly, software devices should continue remaining subject to continual evaluation for interoperability and standardization. Software devices should provide a level of safeguards and standardization to operate safely and efficaciously on any product under QKQ and PSY.

API recommends regulatory evaluation in partnership with digital and computational pathology-enabled organizations like API, DPA, and the Alliance for Digital Pathology<sup>(ref 3)</sup>. Such a cooperative partnership will expedite adequate controls and mitigations to balance innovation safety for AI applications in pathology. Already the FDA has an action plan for AI SaMDs that outlines actions in developing an oversight framework<sup>(ref 13)</sup>. Likewise, an "accommodative" regulatory framework will capture risk events with newly emerging device software while ensuring such devices achieve appropriate interoperability and standardization.

## Reference:

1. <https://www.fda.gov/medical-devices/digital-health-center-excellence/medical-device-interopability>
2. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program>
3. <https://digitalpathologyalliance.org/>
4. <https://www.fda.gov/media/87886/download/>
5. Hanna MG, Reuter VE, Hameed MR, Tan LK, Chiang S, Sigel C, Hollmann T, Giri D, Samboy J, Moradel C, Rosado A, Otilano JR 3rd, England C, Corsale L, Stamelos E, Yagi Y, Schüffler PJ, Fuchs T, Klimstra DS, Sirintrapun SJ. Whole slide imaging equivalency and efficiency study: experience at a large academic center. *Mod Pathol*. 2019 Jul;32(7):916-928.
6. Clarke EL, Munnings C, Williams B, Brett D, Treanor D. Display evaluation for primary diagnosis using digital pathology. *J Med Imaging (Bellingham)*. 2020 Mar;7(2):027501.
7. Abel JT, Ouillette P, Williams CL, Blau J, Cheng J, Yao K, Lee WY, Cornish TC, Balis UGJ, McClintock DS. Display Characteristics and Their Impact on Digital Pathology: A Current Review of Pathologists' Future "Microscope." *J Pathol Inform*. 2020 Aug 11;11:23.
8. Hanna MG, Reuter VE, Ardon O, Kim D, Sirintrapun SJ, Schüffler PJ, Busam KJ, Sauter JL, Brogi E, Tan LK, Xu B, Bale T, Agaram NP, Tang LH, Ellenson LH, Philip J, Corsale L, Stamelos E, Friedlander MA, Ntiamoah P, Labasin M, England C, Klimstra DS, Hameed M. Validation of a digital pathology system including remote review during the COVID-19 pandemic. *Mod Pathol*. 2020 Nov;33(11):2115-2127.
9. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices>
10. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=5535>
11. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=5533>
12. Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD): Discussion Paper and Request for Feedback. Published: April 2019.
13. Artificial Intelligence and Machine Learning (AI/ML) Software as a Medical Device Action Plan. Published: January 2021.

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