
Welcome to the
PIcc meeting
3-14-2021

THE ALLIANCE FOR DIGITAL PATHOLOGY

MGH-MDIC-DPAF

Pathology Innovation Collaborative Community

Plcc

The Alliance for Digital Pathology

436 members; FDA collaborative community

1 of 11 Collaborative Communities with CDRH participation

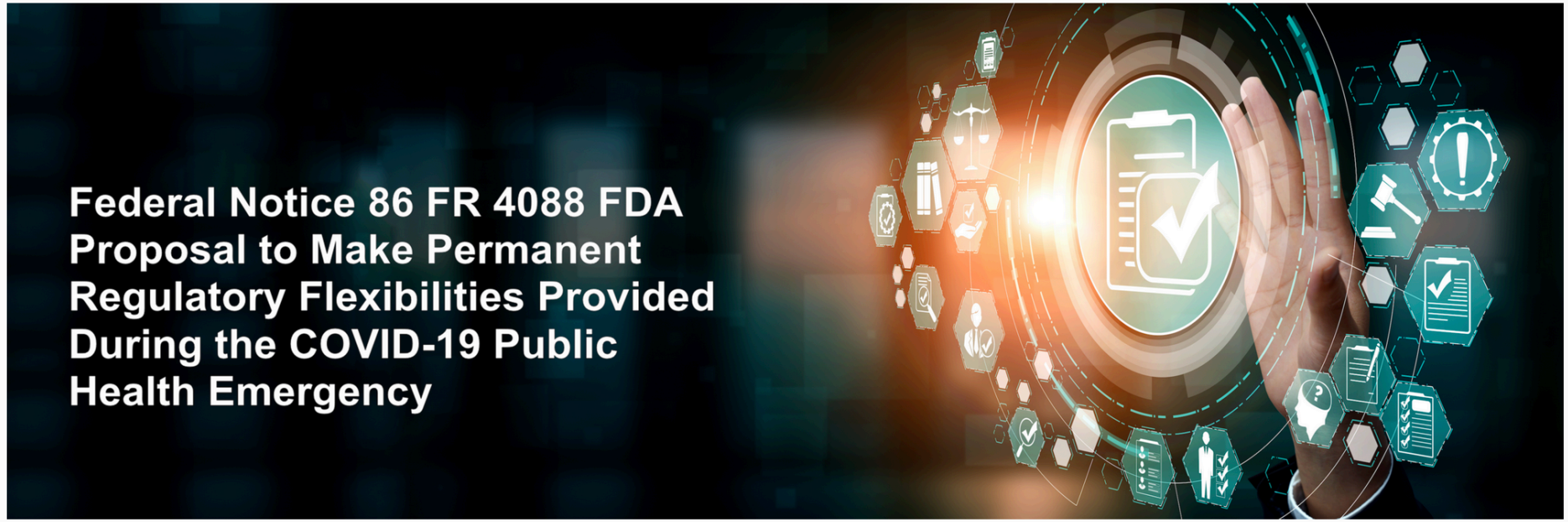
Collaborative Communities with CDRH Participation

The FDA currently participates as a member of these collaborative communities, which have been established and are managed and controlled by external stakeholders.

- Collaborative Community on Ophthalmic Imaging
- National Evaluation System for health Technology Coordinating Center (NESTcc) Collaborative Community
- Standardizing Laboratory Practices in Pharmacogenomics Initiative (STRIPE) Collaborative Community
- International Liquid Biopsy Standardization Alliance (ILSA)
- Xavier Artificial Intelligence (AI) World Consortium
- Case for Quality Collaborative Community
- Heart Valve Collaboratory (HVC)
- Wound Care Collaborative Community
- Pathology Innovation Collaborative Community (PICC)
- RESCUE (REducing SuiCide Rates Amongst IndividUals with DiabEtes) Collaborative Community)

FEBRUARY 8, 2021

Federal Notice 86 FR 4088 FDA Proposal to Make Permanent Regulatory Flexibilities Provided During the COVID-19 PHE



Federal Notice 86 FR 4088 FDA Proposal to Make Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency (link)

by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program

Statement from the "Federal Notice 86 FR 4088 Workgroup"
(available for download in editable form here)

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Notice

Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program

A Notice by the Food and Drug Administration on 01/15/2021

Comments on this document are being accepted at Regulations.gov.

SUBMIT A FORMAL COMMENT

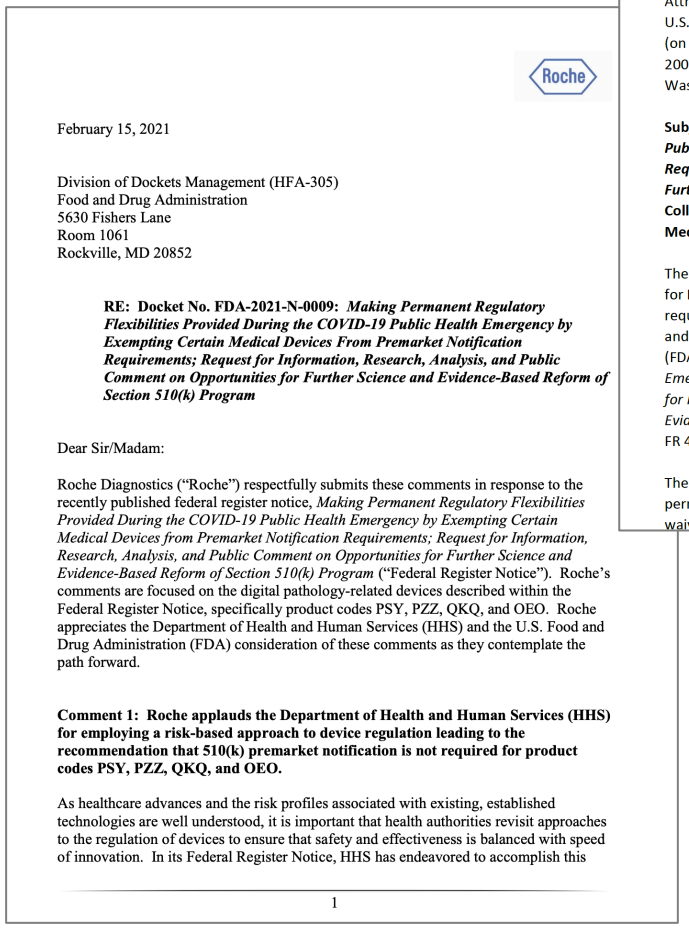
Read the 39 public comments

PUBLISHED DOCUMENT

Detailed breakdown

Device Description	Exemption	Class	Product Code	21 CFR Secti	Agree	# devices cleared	Comment
Powder-Free Polychloroprene Patient Examination Glove	Class I, Immediate 510(k) Exemption	I	OPC	880.625	Y	0	No Comment
Patient Examination Glove, Specialty	Class I, Immediate 510(k) Exemption	I	LZC	880.625	N	200	Chemotherapy drugs have capacity to leach through gloves and absorb int
Radiation Attenuating Medical Glove	Class I, Immediate 510(k) Exemption	I	OPH	880.625	N	0	Risks of radiation exposure relate to the design of the gloves
Powder-Free Non-Natural Rubber Latex Surgeon''s Gloves	Class I, Immediate 510(k) Exemption	I	OPA	878.446	N	0	Surgical gloves are first point of patient contact. These gloves are intended
Powder-Free Guayle Rubber Examination Glove	Class I, Immediate 510(k) Exemption	I	OIG	880.625	Y	1	No Comment
Latex Patient Examination Glove	Class I, Immediate 510(k) Exemption	I	LYY	880.625	Y	500	No Comment
Vinyl Patient Examination Glove	Class I, Immediate 510(k) Exemption	I	LYZ	880.625	Y	500	No Comment
Ventilator, Continuous, Minimal Ventilatory Support, Home Use	Class II, Unclassified Proposed 510(k) Exemption	II	NQY	868.5895	N	0	This is a life supporting and life sustaining device with incre Since this device has a small number of devices cleared by t
Airway Monitoring System	Class II, Unclassified Proposed 510(k) Exemption	II	OQU	868.573	N	3	There are potential risks which should be mitigated during design as well Since this device has a small number of devices cleared by the FDA, the e
Impedance Measuring Device Utilizing Oscillation Techniques	Class II, Unclassified Proposed 510(k) Exemption	II	PNV	868.184	Y	3	No Comment
Gauge, Pressure, Coronary, Cardiopulmonary Bypass	Class II, Unclassified Proposed 510(k) Exemption	II	DXS	870.431	N	15	Accessory to life supporting device. There are potential risk Since this device has a small number of devices cleared by t
Valve, Pressure Relief, Cardiopulmonary Bypass	Class II, Unclassified Proposed 510(k) Exemption	II	MNJ	870.44	N	2	There are potential risks which should be mitigated during design as well Since this device has a small number of devices cleared by the FDA, the e
Oximeter, Tissue Saturation, Reprocessed	Class II, Unclassified Proposed 510(k) Exemption	II	NMD	870.27	N	2	There are potential risks which should be mitigated during design as well Since this device has a small number of devices cleared by the FDA, the e
Multivariate Vital Signs Index	Class II, Unclassified Proposed 510(k) Exemption	II	PLB	870.23	N	6	There are potential risks which should be mitigated during design as well Since this device has a small number of devices cleared by the FDA, the e
Electrocardiograph Software For Over-The-Counter Use	Class II, Unclassified Proposed 510(k) Exemption	II	QDA	870.2345	N	5	Since this device has a small number of devices cleared by t
Sterilizer, Dry Heat	Class II, Unclassified Proposed 510(k) Exemption	II	KMH	880.687	N	10	Since this device has a small number of devices cleared by the FDA, the e
Check Valve, Retrograde Flow (In-Line)	Class II, Unclassified Proposed 510(k) Exemption	II	MJF	880.544	N	1	Contact blood circulatory system. Since this device has a small number of devices cleared by the FDA, the e
Intravascular Administration Set, Automated Air Removal System	Class II, Unclassified Proposed 510(k) Exemption	II	OKL	880.5445	N	1	Design issues may allow air to remain in the system causing an air embol Since this device has a small number of devices cleared by the FDA, the e
Neuraxial Administration Set—Intrathecal Delivery	Class II, Unclassified Proposed 510(k) Exemption	II	PYR	880.544	N	1	Inrathecal delivery in intended for the space between the thi Since this device has a small number of devices cleared by t
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Liquid	Class II, Unclassified Proposed 510(k) Exemption	II	PSW	892.157	N	5	There have been significant issues with infection caused by inadequate dis

Total of 39 comments



February 15, 2021

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2021-N-0009: *Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program*

Dear Sir/Madam:

Roche Diagnostics ("Roche") respectfully submits these comments in response to the recently published federal register notice, *Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices from Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program* ("Federal Register Notice"). Roche's comments are focused on the digital pathology-related devices described within the Federal Register Notice, specifically product codes PSY, PZZ, QKQ, and OEO. Roche appreciates the Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) consideration of these comments as they contemplate the path forward.

Comment 1: Roche applauds the Department of Health and Human Services (HHS) for employing a risk-based approach to device regulation leading to the recommendation that 510(k) premarket notification is not required for product codes PSY, PZZ, QKQ, and OEO.

As healthcare advances and the risk profiles associated with existing, established technologies are well understood, it is important that health authorities revisit approaches to the regulation of devices to ensure that safety and effectiveness is balanced with speed of innovation. In its Federal Register Notice, HHS has endeavored to accomplish this

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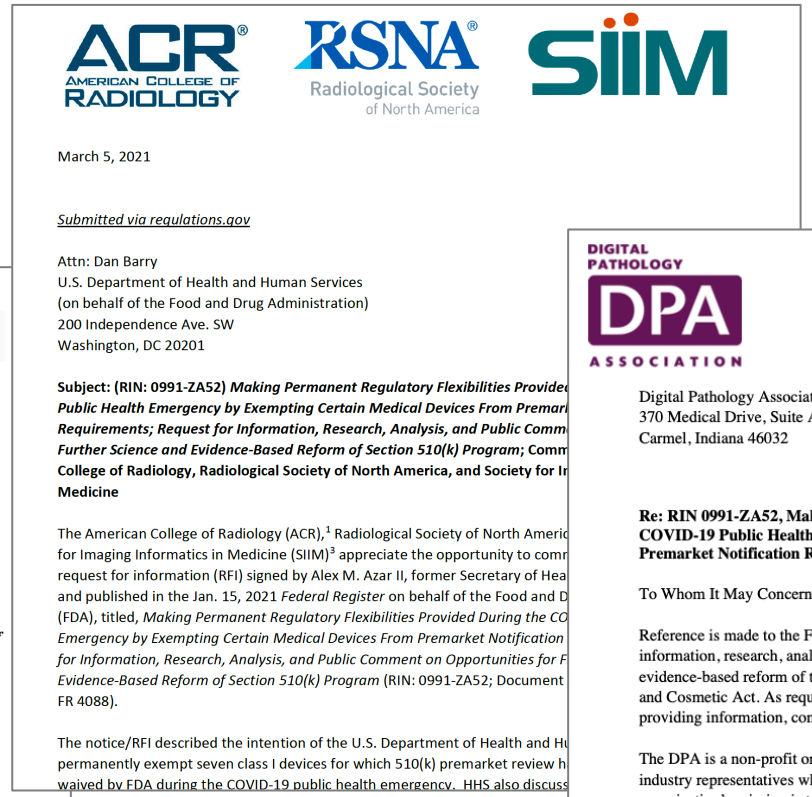


March 5, 2021

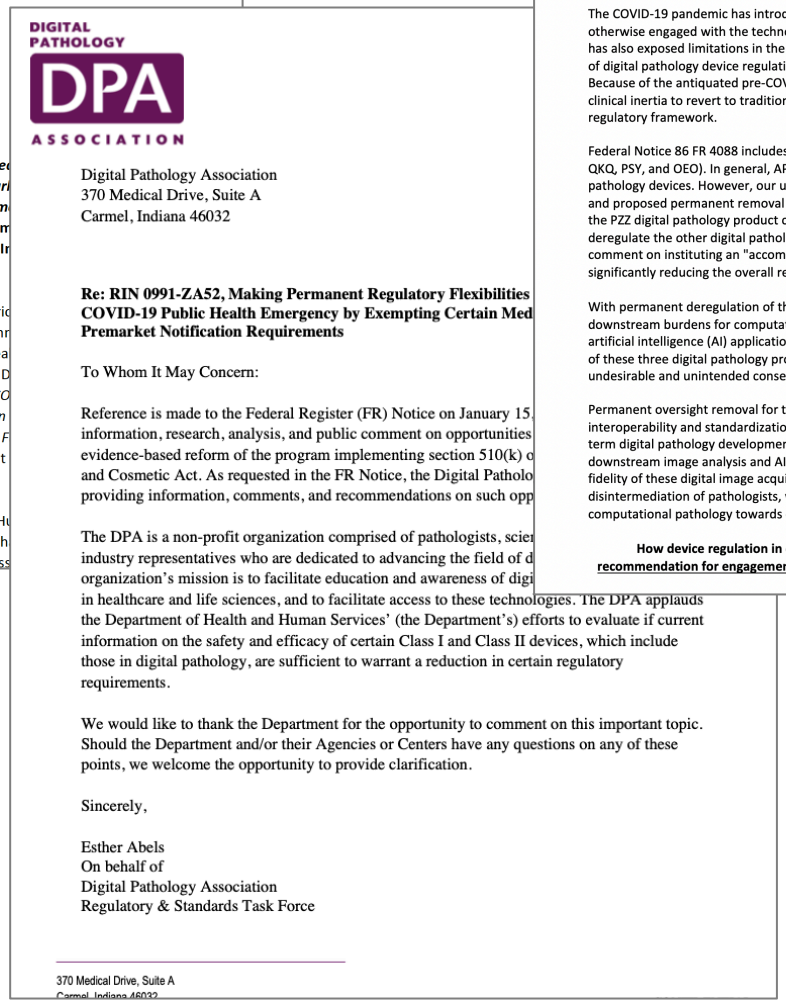
Submitted via regulations.gov

Attn: Dan Barry
U.S. Department of Health and Human Services
(on behalf of the Food and Drug Administration)
200 Independence Ave. SW
Washington, DC 20201

Subject: (RIN: 0991-ZA52) *Making Permanent Regulatory Flexibilities Provide*
Public Health Emergency by Exempting Certain Medical Devices From Premar
Requirements; Request for Information, Research, Analysis, and Public Comm
***Further Science and Evidence-Based Reform of Section 510(k) Program*; Comm**
College of Radiology, Radiological Society of North America, and Society for In
Medicine

The American College of Radiology (ACR),[1] Radiological Society of North Americ
for Imaging Informatics in Medicine (SIIM)[3] appreciate the opportunity to comm
request for information (RFI) signed by Alex M. Azar II, former Secretary of Hea
and published in the Jan. 15, 2021 *Federal Register* on behalf of the Food and D
(FDA), titled, *Making Permanent Regulatory Flexibilities Provided During the CO*
Emergency by Exempting Certain Medical Devices From Premarket Notification
for Information, Research, Analysis, and Public Comment on Opportunities for F
Evidence-Based Reform of Section 510(k) Program (RIN: 0991-ZA52; Document
FR 4088).

The notice/RFI described the intention of the U.S. Department of Health and Hu
permanently exempt seven class I devices for which 510(k) premarket review h
waived by FDA during the COVID-19 public health emergency. HHS also discuss



Digital Pathology Association
370 Medical Drive, Suite A
Carmel, Indiana 46032

Re: RIN 0991-ZA52, Making Permanent Regulatory Flexibilities
COVID-19 Public Health Emergency by Exempting Certain Med
Premarket Notification Requirements

To Whom It May Concern:

Reference is made to the Federal Register (FR) Notice on January 15,
information, research, analysis, and public comment on opportunities
evidence-based reform of the program implementing section 510(k) o
and Cosmetic Act. As requested in the FR Notice, the Digital Patholo
providing information, comments, and recommendations on such opp

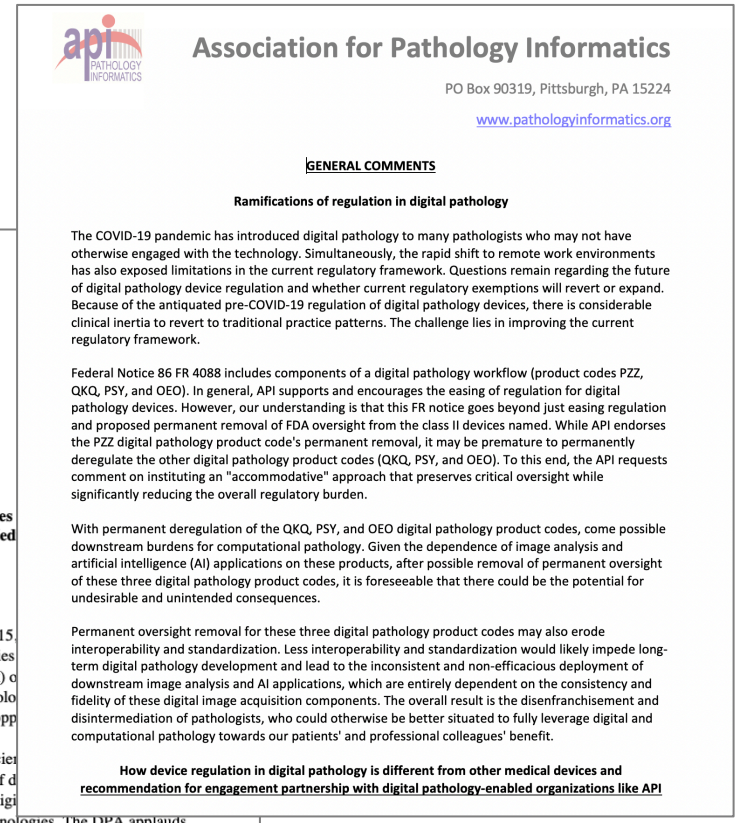
The DPA is a non-profit organization comprised of pathologists, scie
industry representatives who are dedicated to advancing the field of d
organization's mission is to facilitate education and awareness of digi
in healthcare and life sciences, and to facilitate access to these technologies. The DPA applauds the Department of Health and Human Services' (the Department's) efforts to evaluate if current information on the safety and efficacy of certain Class I and Class II devices, which include those in digital pathology, are sufficient to warrant a reduction in certain regulatory requirements.

We would like to thank the Department for the opportunity to comment on this important topic. Should the Department and/or their Agencies or Centers have any questions on any of these points, we welcome the opportunity to provide clarification.

Sincerely,

Esther Abels
On behalf of
Digital Pathology Association
Regulatory & Standards Task Force

370 Medical Drive, Suite A
Carmel, Indiana 46032



Association for Pathology Informatics

PO Box 90319, Pittsburgh, PA 15224

www.pathologyinformatics.org

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

Registration Form: Click here

Meeting Agenda:

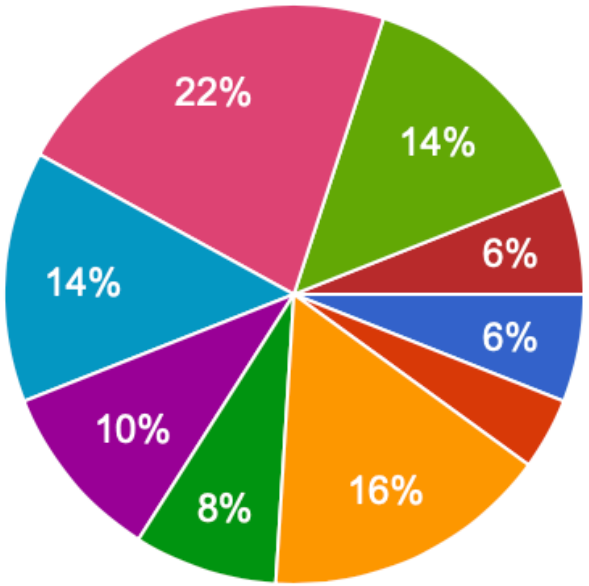
- 15’ Meet & Greet
- 60’ Workgroup Breakout Sessions – interactive breakout rooms that allow hopping from room to room
    - Review website content
    - Review deliverables and relevance
    - Coming together in a bigger group to provide updates
- 15’ Transition time
- 45’ Workgroup summaries (5’ each)
- 15’ Discussion

Working Groups

Today ☺

Which breakout session would you like to join?

50 responses



- Pre-Analytics
- Truthing Data Sets
- Slide Scanning
- Continuous Learning
- Data Standardization
- Practical Use Cases
- ML/AI - Model Creation
- Payor
- Trainees