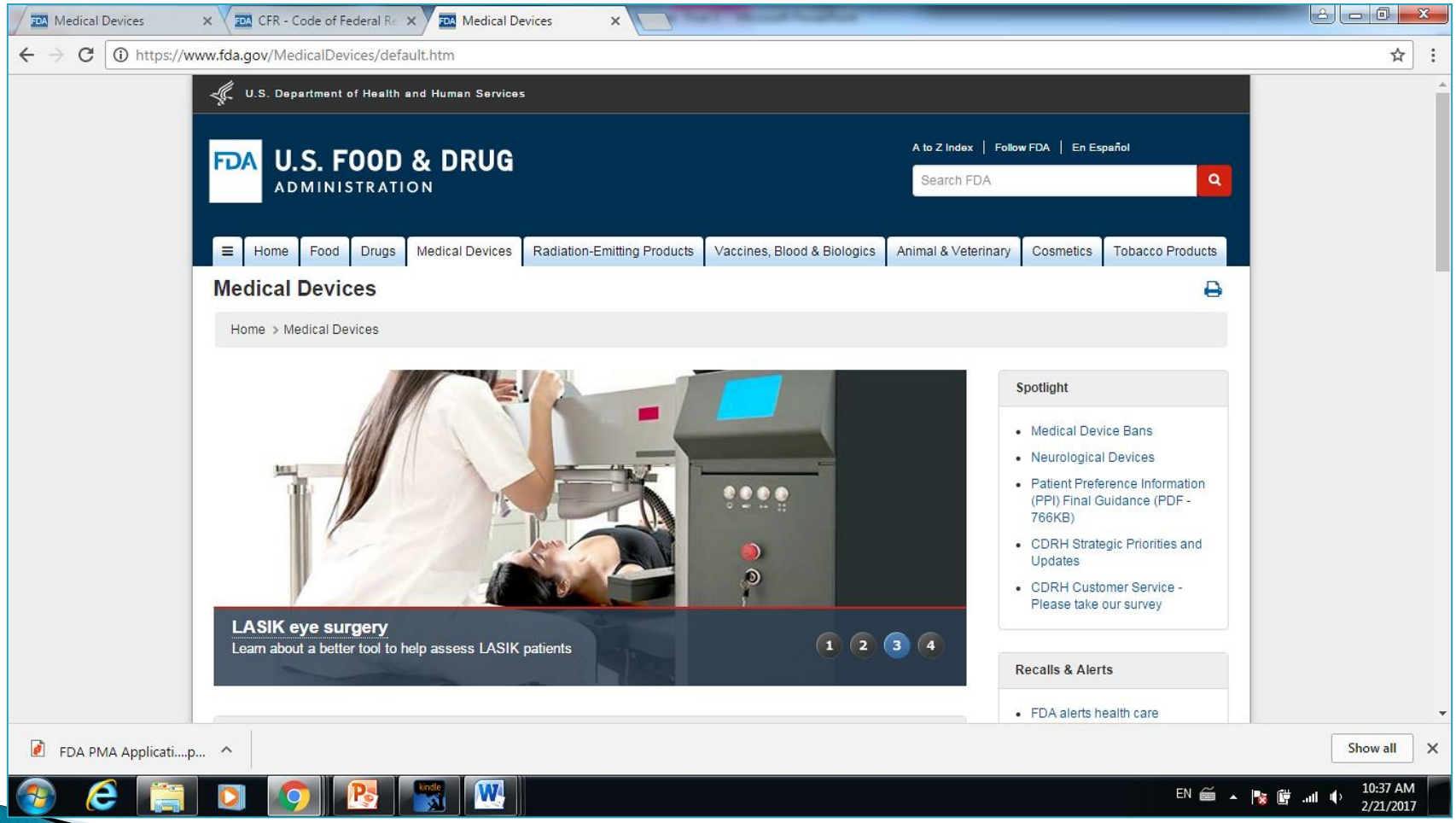
Classification of Medical Devices and FDA Approval Process

The FDA and Regulation of Medical Devices
Define a Medical Device
Steps in the FDA Approval Process
Device Class and Submissions
Good Manufacturing Practice: Labeling, Packaging, etc.

The FDA and the Regulation of Medical Devices: FDA's Role

- The FDA is a branch of the department of Health and Human Services.
- The FDA thus is a government body.
- The main role of the FDA is that of regulation.
- Food, Cosmetics, Radiation and emitting products as well as Medical devices are some of the products the FDA regulates.
- No regulated product may be marketed in the United States without the approval of the FDA.

The FDA Regulates Medical Devices



The FDA and the Regulation of Medical Devices: The FDA's Role

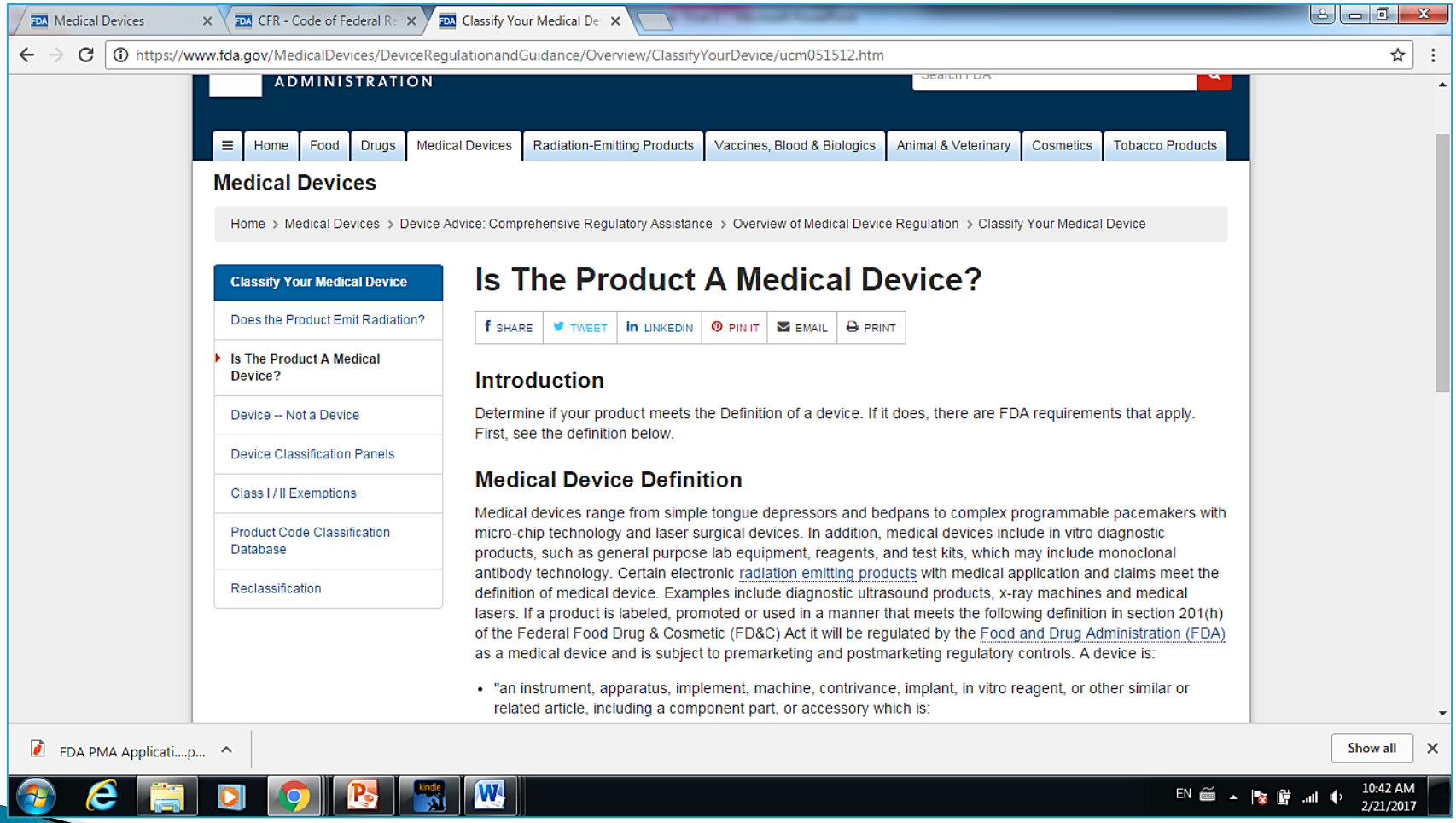
- The FDA uses the results of tests performed according to standards it has approved to help it with the approval process.
- These standards are not written by the FDA, though the FDA may contribute in the process.
- The FDA has a list of approved standards available at its website.
- Marketing an unapproved regulated product can lead to severe sanctions against the violator.

The FDA and the Regulation of Medical Devices: Definition of a Medical Device

- The FDA Defines a Medical Device as: An Instrument, Apparatus, Implement, Machine, Contrivance, Implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

FDA's Definition of a Medical Device



The FDA and the Regulation of Medical Devices: Definition of a Medical Device

- Intended for use in the Diagnosis of Disease or other conditions, or in the Cure, Mitigation, Treatment, or Prevention of Disease, in Man or other Animals.

The FDA and the Regulation of Medical Devices: Definition of a Medical Device

- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

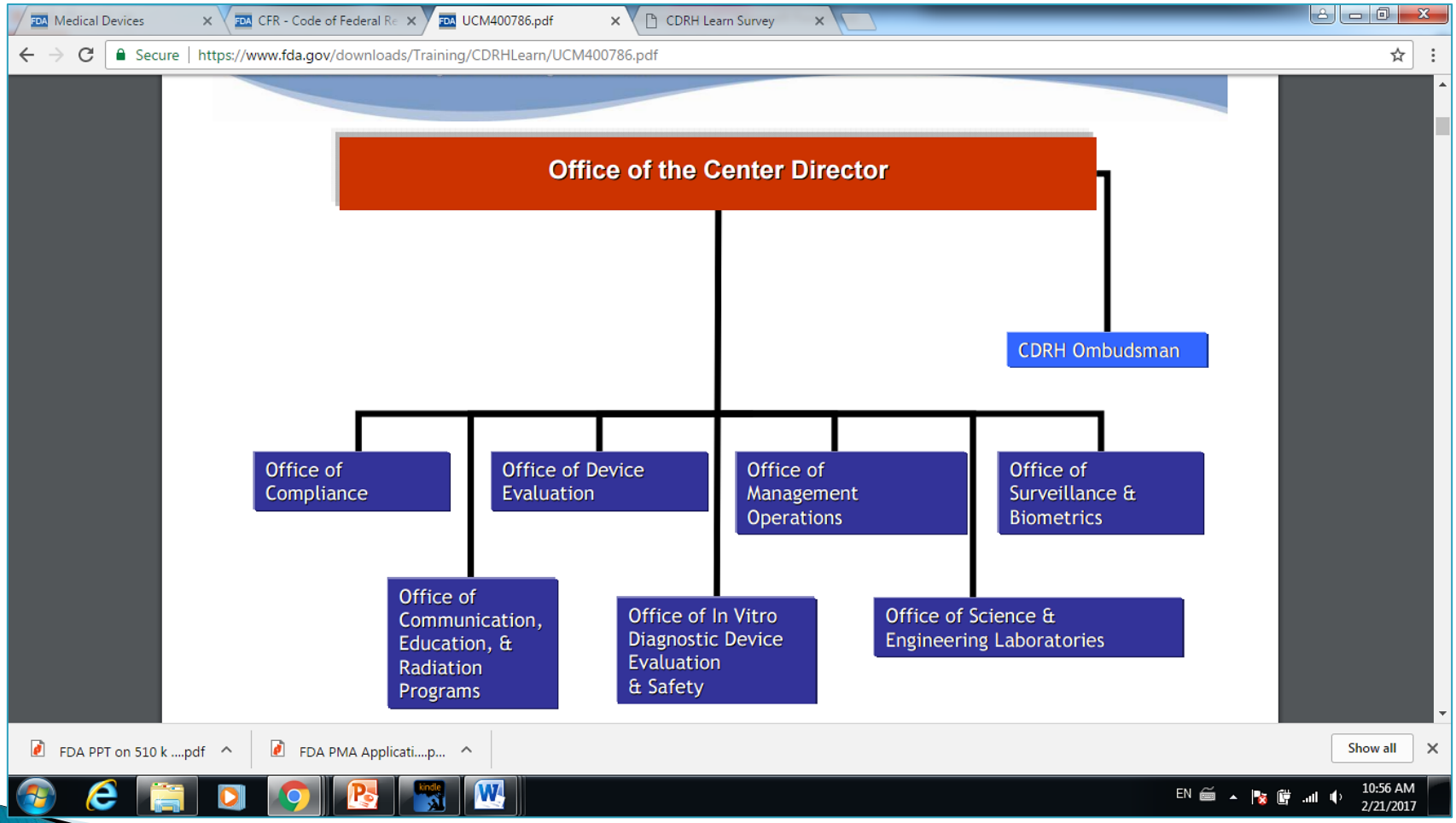
The FDA and the Regulation of Medical Devices: Regulated Industry Sectors

- The FDA regulates the Medical Device companies that :
- Design
- Manufacture
- Relabel
- Repackage
- And/or Import Medical Devices into the United States.

The FDA and the Regulation of Medical Devices: The CDRH

- The FDA's Center for Devices and Radiological Health(CDRH), is charged with the Regulations.
- The CDRH is responsible for assuring the safety, effectiveness, and quality of medical devices, including those that emit electromagnetic waves.
- The CDRH also strives to foster innovations as pertaining to medical devices.
- The center has a director.

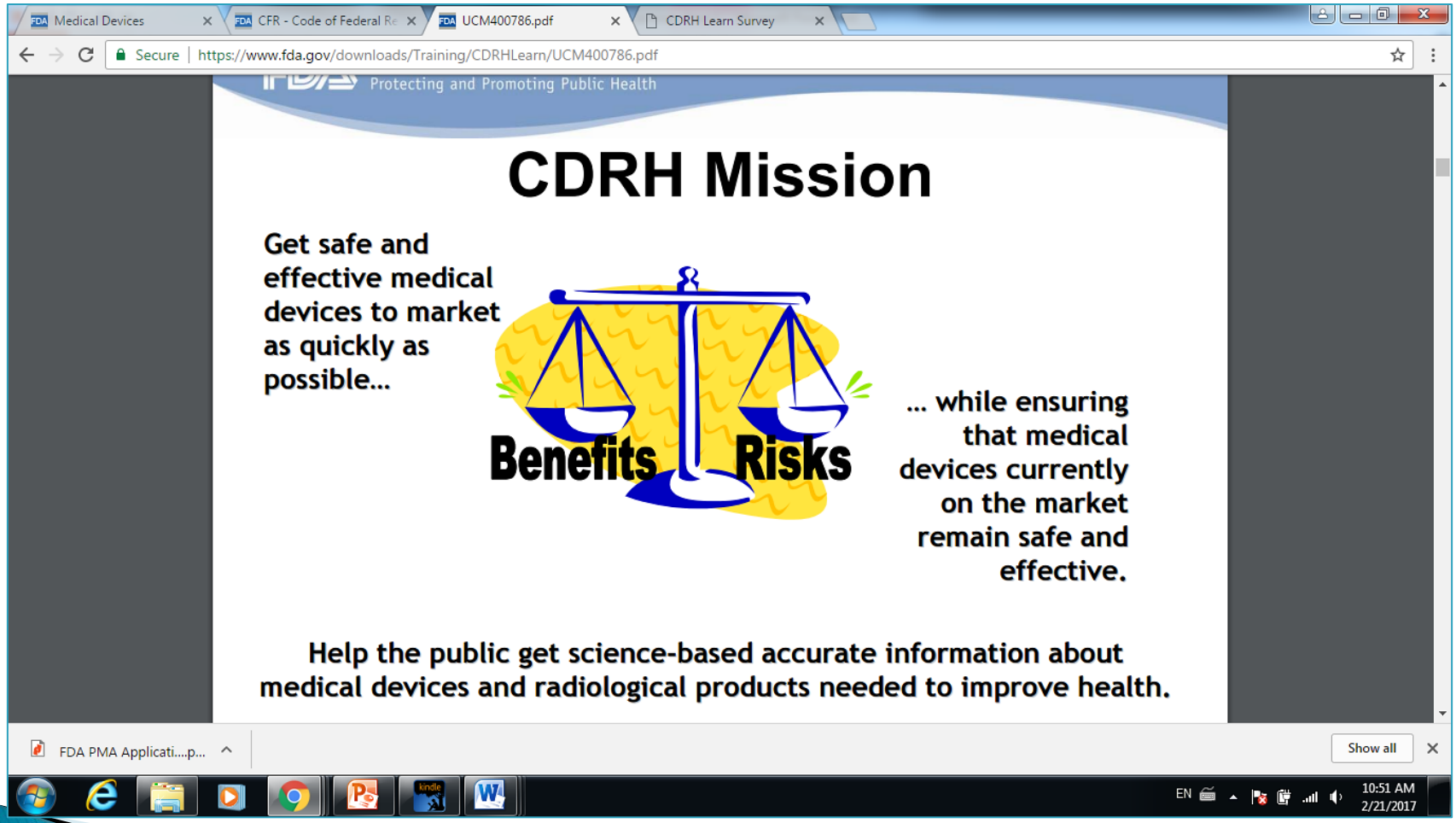
CDRH Offices



The FDA and the Regulation of Medical Devices: The CDRH

- The CDRH has eight offices, that taken together perform the regulation functions.
- The CDRH Office of Compliance(OC), is composed of five divisions, including:
- Premarket and Labeling Compliance(DPLC), Manufacturing and Quality(DMQ), International Compliance Operation(DIO), etc.
- Each of the five divisions plays a particular role in protecting the public health by "evaluating, enhancing, and ensuring compliance with medical device laws, resulting in the availability of high-quality medical devices."

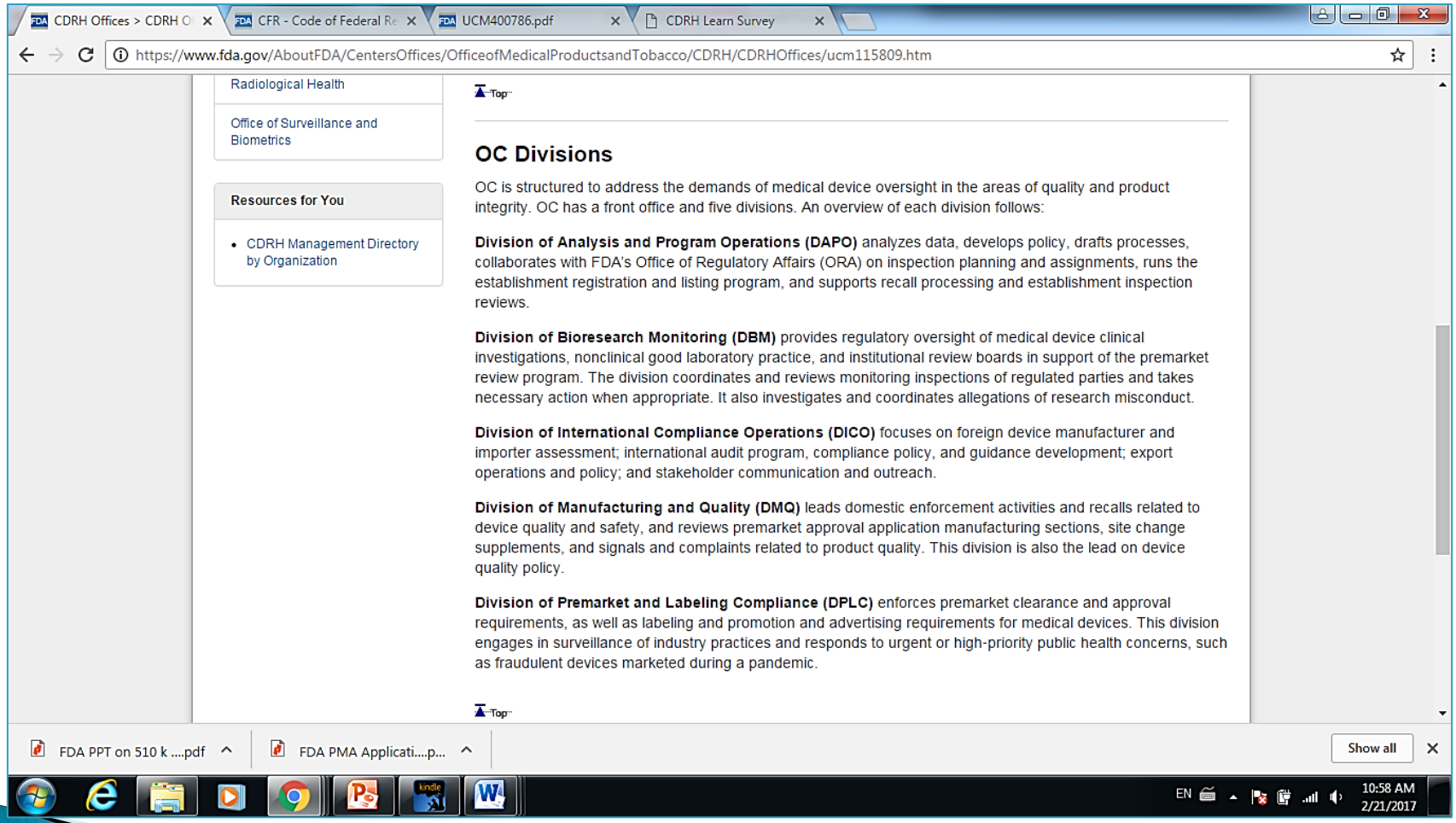
CDRH's Missions According to the FDA



The FDA and the Regulation of Medical Devices: The DPLC

- The DPLC in particular is responsible for:
- Enforcing premarket clearance and approval requirements, as well as
- labeling and promotion and advertising requirements for medical devices.
- It engages in surveillance of industry practices and responds to urgent or high-priority public health concerns, such as fraudulent devices marketed during a pandemic.

Office of Compliance(OC): Divisions



The FDA and the Regulation of Medical Devices: Device Classes

- To expedite the approval process it is important to know the device class prior to filling for PMA, 510(K) or other submissions.
- The FDA categorized medical devices into three classes, Class I, Class II and Class III.
- These classes are assigned based on the risk associated with the device, with the degree of severity increasing from class I

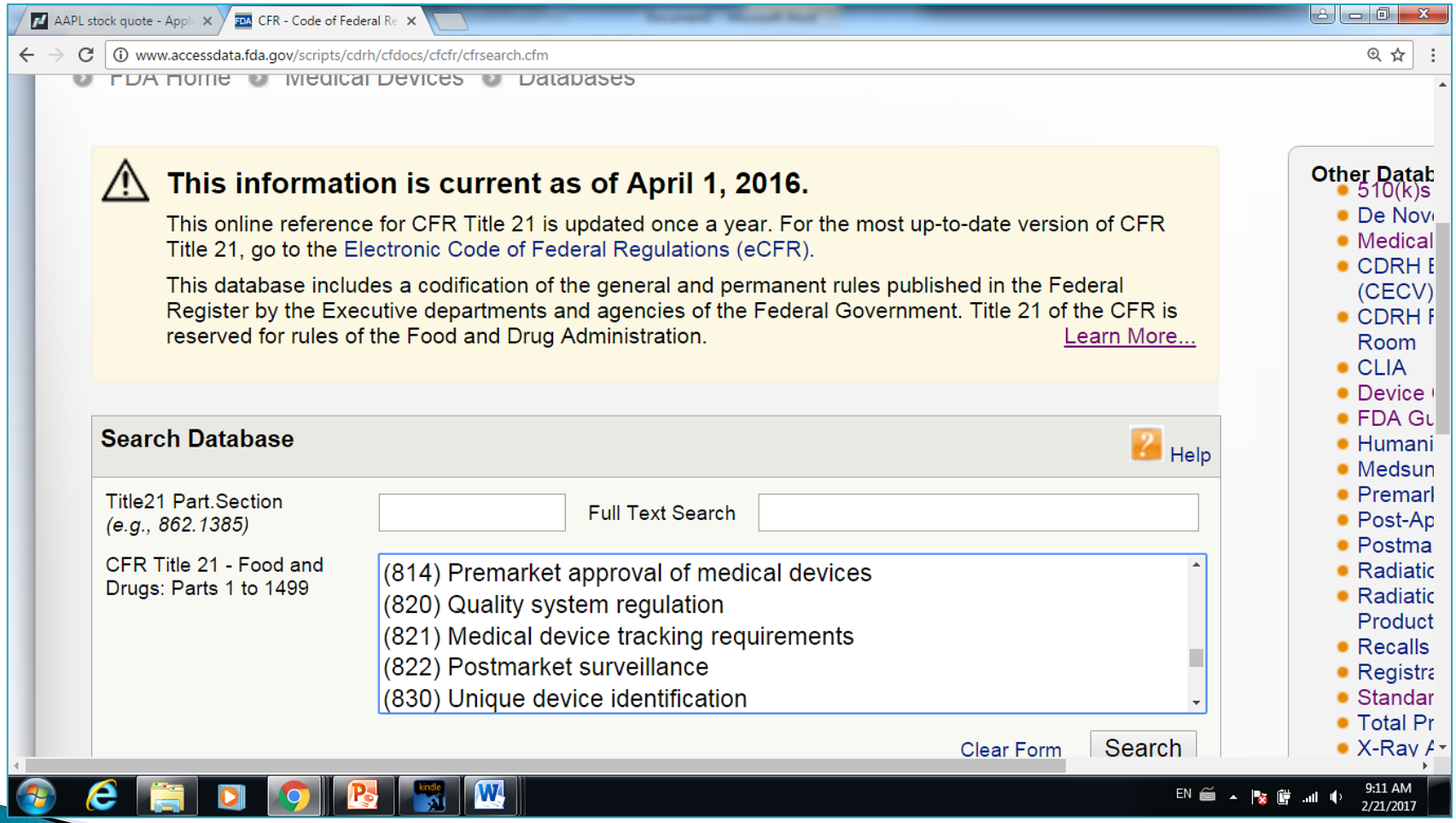
The FDA and the Regulation of Medical Devices: Device Classes

- Class I devices are associated with the least risks. The stringency of the regulation required for class I devices is consequently the least.
- Class II devices come with increasing associated risks, and are more rigorously regulated.
- The class of devices associated with the highest risks and regulatory controls are those in class III. Devices in this class must typically meet FDA approval prior to their being marketed to the public

The FDA and the Regulation of Medical Devices: Code of Federal Regulation

- All medical devices marketed in the United States are subject to the regulatory control in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the regulations in Title 21–Code of Federal Regulations (21 CFR) Parts 1–58, 800–1299.
- Part 1 is: General Enforcement Regulations.
- Part 800s: Medical Device Concentrated parts.
- Each Part has several subparts.
- The requirements are termed “Premarket Requirements” if they apply to the medical device prior to its marketing, or “Post-market Requirements”, if they apply after the medical device has been marketed.

CFR Title 21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Databases
This information is current as of April 1, 2016.
This online reference for CFR Title 21 is updated once a year. For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).
This database includes a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration.
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(822) Postmarket surveillance
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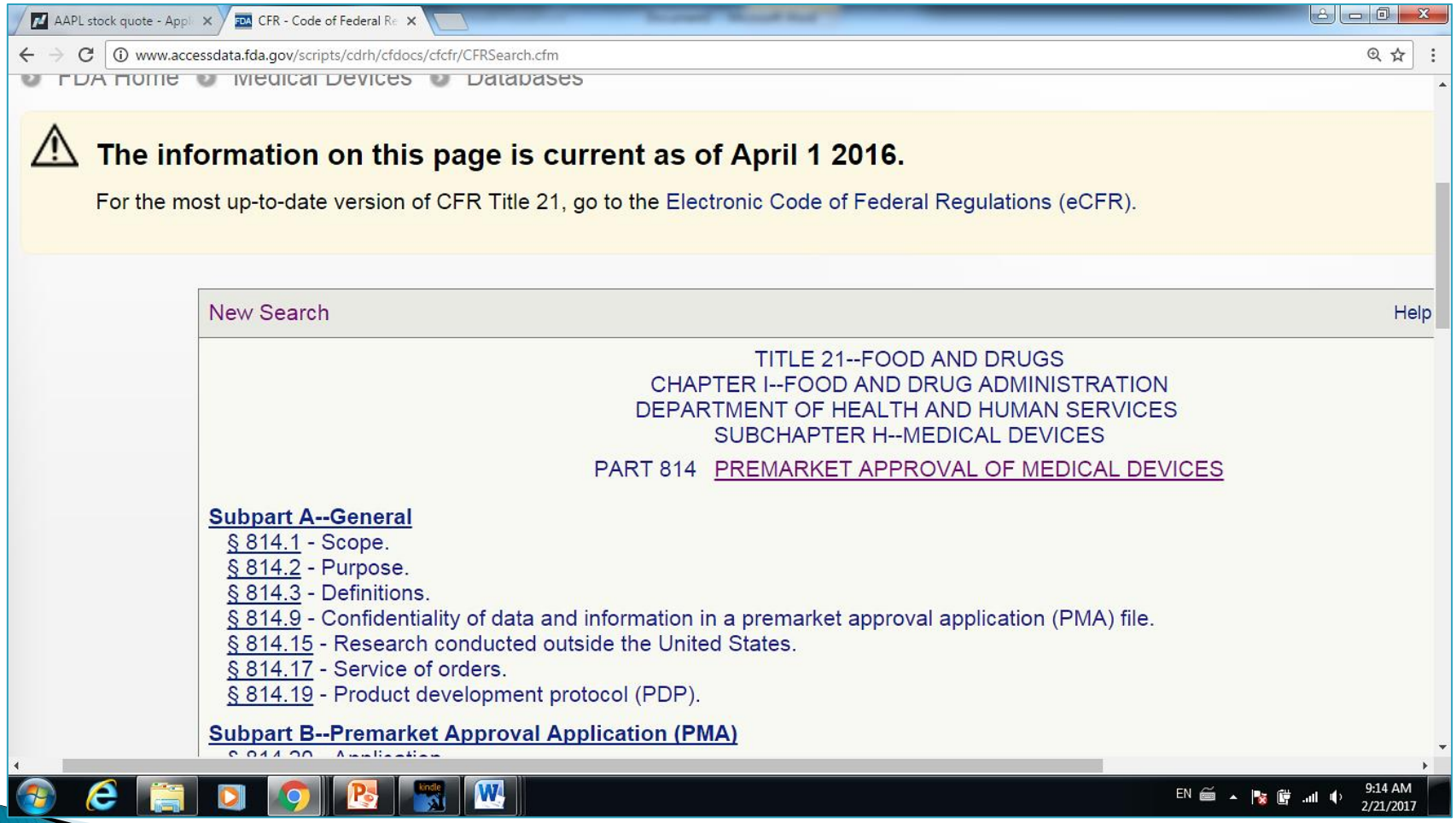
The FDA and the Regulation of Medical Devices: Premarket Requirements

- If Premarket Requirements apply to a Medical Device, then it is necessary to know the device class to begin the process, as well as all the other steps needed.
- The following are Premarket Requirements:
- Step 1: Classify the Device
- Step 2: Chose the Correct Premarket Submission

The FDA and the Regulation of Medical Devices: Premarket Requirements

- Step 3: Prepare the Appropriate Information for the Premarket Submission to the FDA
- Step 4: Send the Premarket Submission to the FDA and Interact with FDA Staff during Review.
- Step 5: Complete the Establishment Registration and Device Listing

Premarket Requirement



The FDA and the Regulation of Medical Devices: Device Classification Steps

- The following steps may be used to classify a medical device,
- knowing the device class may help in expediting the approval process for that device; However:
- The FDA officially classifies a medical device when reviewing the premarket submission.
- Once a device is classified, the regulations and exemptions that apply are known. This information may then help in the premarket submission.

The FDA and the Regulation of Medical Devices: Device Classification Steps

- Step 1: Obtain the regulatory Citation Part number of the device. This information can be obtained from the "Device Panel" feature available on the FDA website.
- The Table provided lists Device Specialty Ranging from Anesthesiology, with a Regulation Citation(21CFR), part 868, to Toxicology, with a Regulation citation(21CFR), part 882.

Device Classification Panel

Medical Specialty		Regulation Citation (21CFR)
73	Anesthesiology	Part 868
74	Cardiovascular	Part 870
75	Chemistry	Part 862
76	Dental	Part 872
77	Ear, Nose, and Throat	Part 874
78	Gastroenterology and Urology	Part 876
79	General and Plastic Surgery	Part 878
80	General Hospital	Part 880
81	Hematology	Part 864
82	Immunology	Part 866
83	Microbiology	Part 866
84	Neurology	Part 882
85	Obstetrical and Gynecological	Part 884
86	Ophthalmic	Part 886
87	Orthopedic	Part 888
88	Pathology	Part 864
89	Physical Medicine	Part 890
90	Radiology	Part 892
91	Toxicology	Part 862

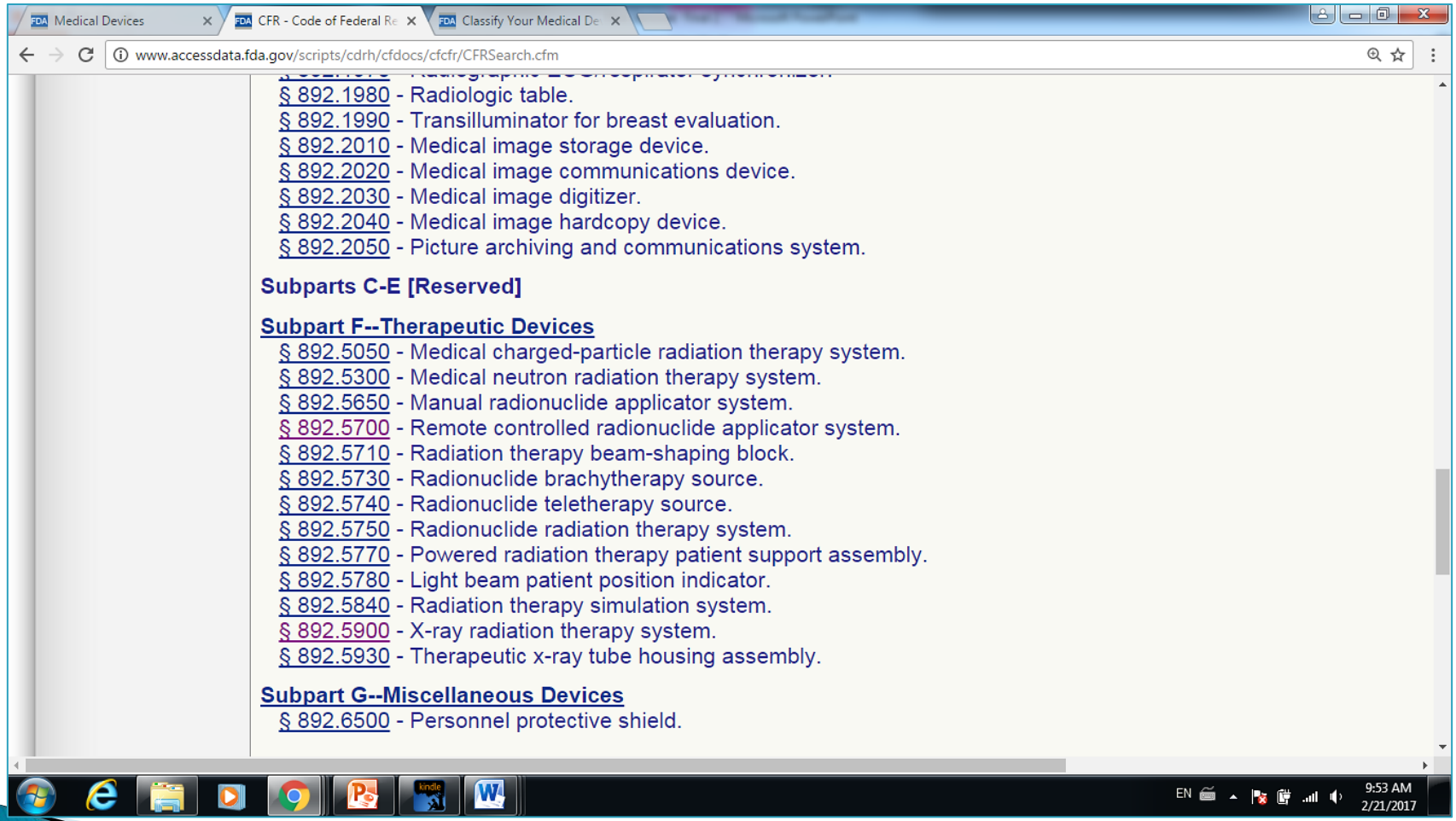
The FDA and the Regulation of Medical Devices: Device Classification process

- Once the medical specialty for the device is identified, the Regulation Citation(21 CFR) is accessed as needed.
- The Regulation citation for the device specialty, contains information on the scope, effective dates of requirements for premarket approval, limitation of exemptions from 510(K) in subpart A.
- The remaining subparts are devices specific- used to pinpoint the class of the device.

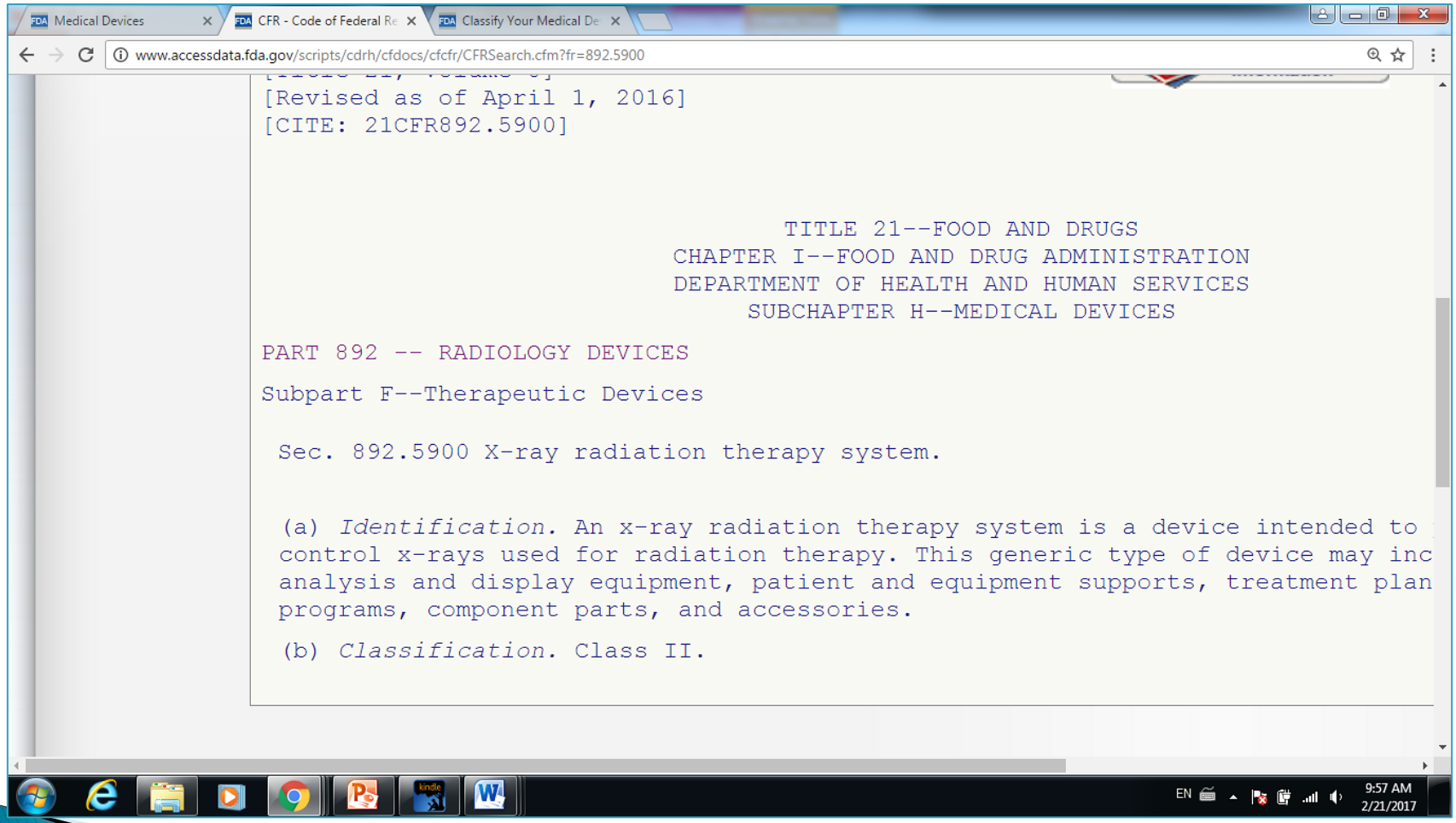
The FDA and the Regulation of Medical Devices: Device Classification Process

- Example: a therapeutic x-ray device:
- It will belong to the radiology medical specialty, with Regulation Citation 892.
- Upon accessing the citation database, the scope, effective dates for premarket approval and exemption information are given in subpart A, the general provision.
- The actual class of the device is obtained by locating the device under the appropriate subpart, in this case subpart F, therapeutic device, select 892-5900. The class x-radiation therapy system. The device identification and classification II, is given.

Classification Process example: X-Radiation Therapy System



Classification Process example: X-Radiation Therapy System



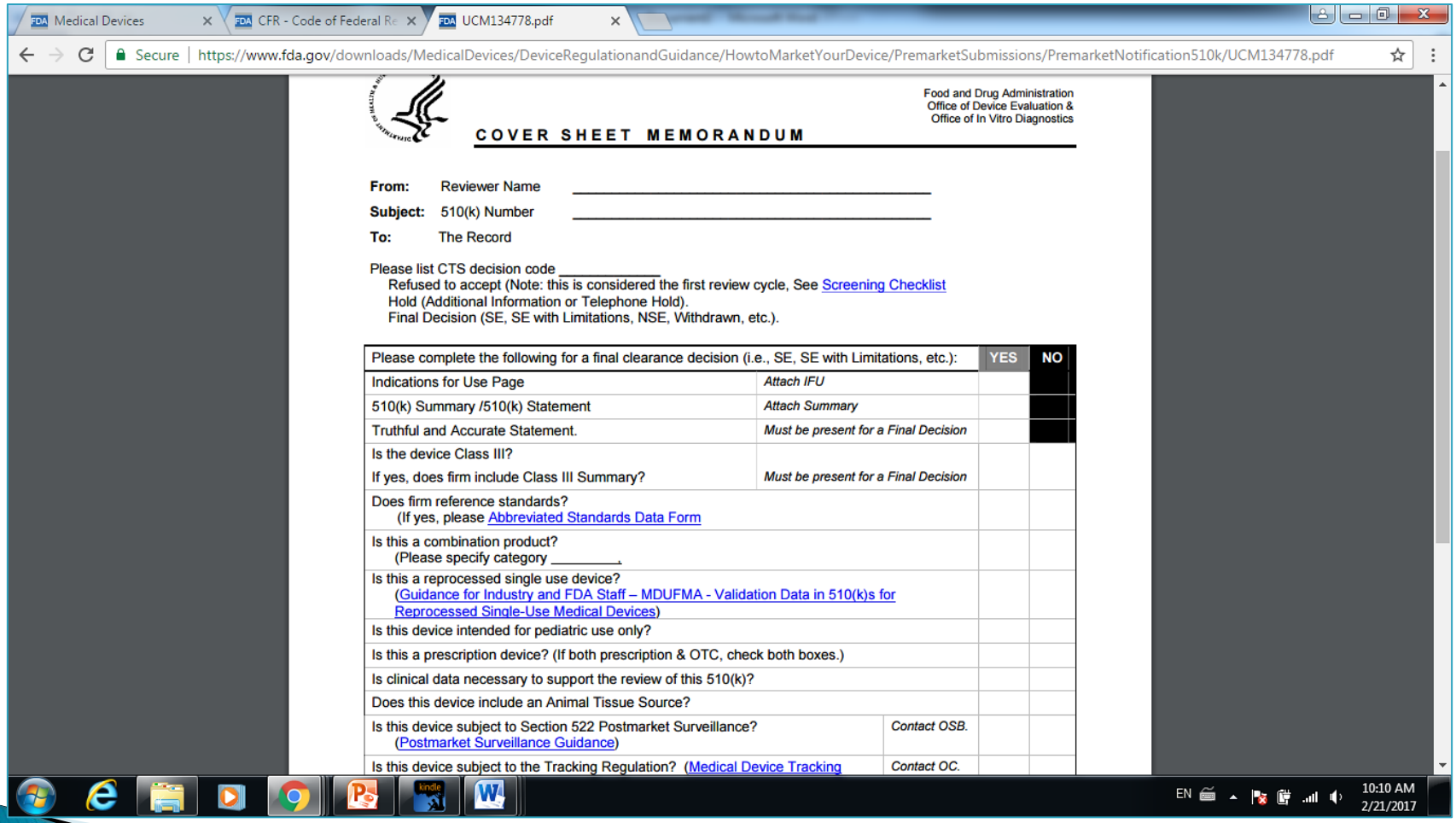
FDA Regulation of Medical Devices: Premarket Submission

- Premarket Submission Types include:
- 510(K): Premarket Notification
- PMA: Premarket Approval
- HDE : Humanitarian Device Exemption
- De Novo: Evaluation of Automatic Class III Designation
- The device class partially determines the Premarket Submission Type.

FDA Regulation of Medical Devices: Premarket Submission: 510(k)

- 510(k):
- Applicable for certain class I and class II devices, but not class III devices.
- Substantial Equivalency of the device for which approval is seek to a predicate device must be proven.
- Substantial Equivalency applies to the technological characteristics and performance testing for the devices.
- Some class I and class II devices are exempt from 510(k), if they do not exceed the limitations of exemption stated in the applicable 21 CFR xxx.9.

510(k) Cover Sheet Memorandum



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Secure | https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/UCM134778.pdf

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name _____

Subject: 510(k) Number _____

To: The Record

Please list CTS decision code _____
Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
Hold (Additional Information or Telephone Hold).
Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please Abbreviated Standards Data Form			
Is this a combination product? (Please specify category _____.			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking	*Contact OC.*		

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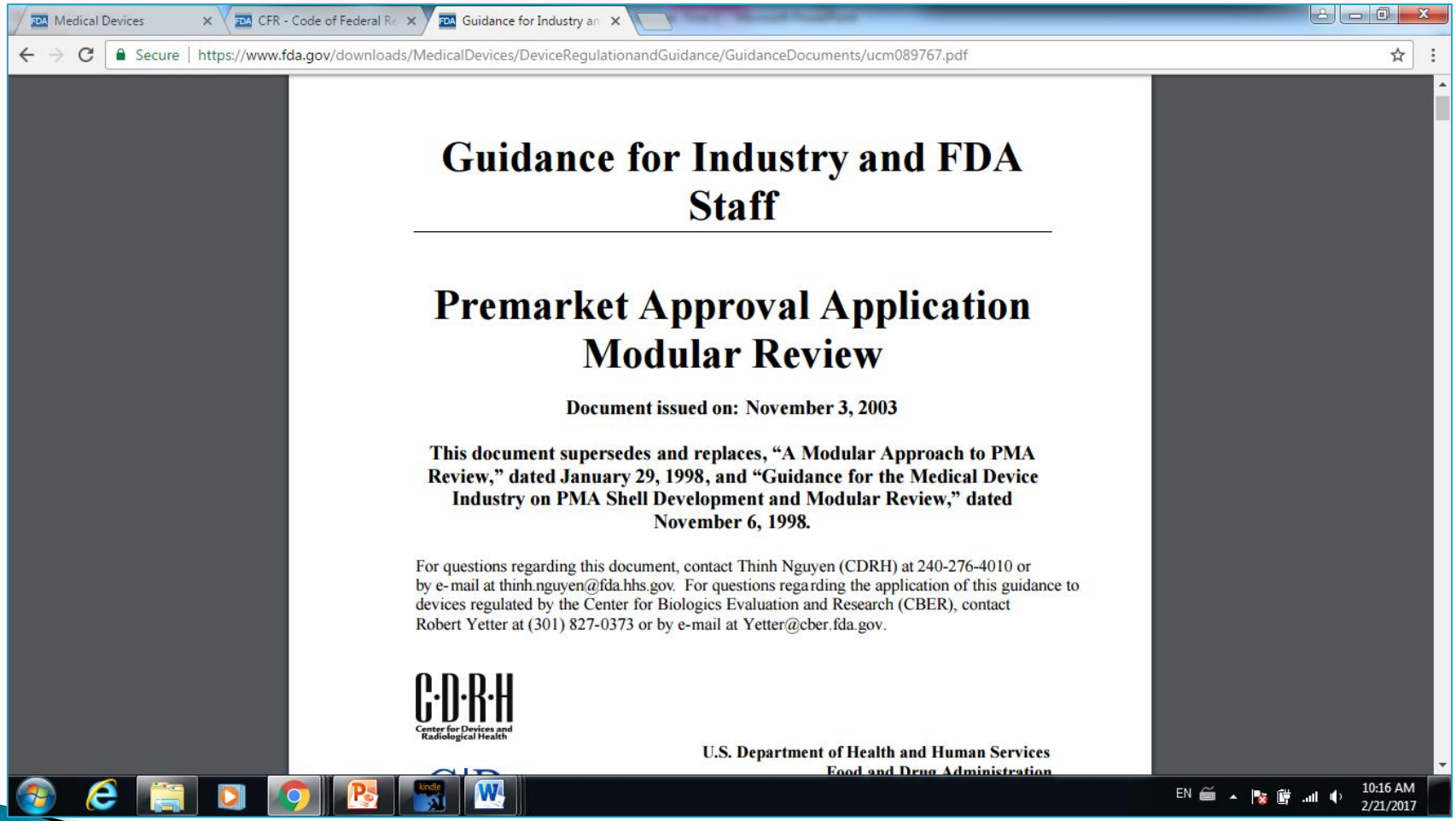
FDA Regulation of Medical Devices: Premarket Submission: PMA

- PMA:
- This is the most stringent of the premarket submissions.
- A PMA is required for most class III devices
- A valid scientific evidence demonstrating reasonable assurance of safety and effectiveness for the device's intended use is required before approval can be granted for a PMA device.

PMA Application Guidance



FDA Regulation of Medical Devices: Premarket Submission: HDE

- HDE:
- This applies for class III devices, if such a device is intended to be used to benefit patients with rare diseases or conditions.
- A device for which an HDE premarket submission is being seek, must first have obtained the Humanitarian Use Device (HUD) designation.

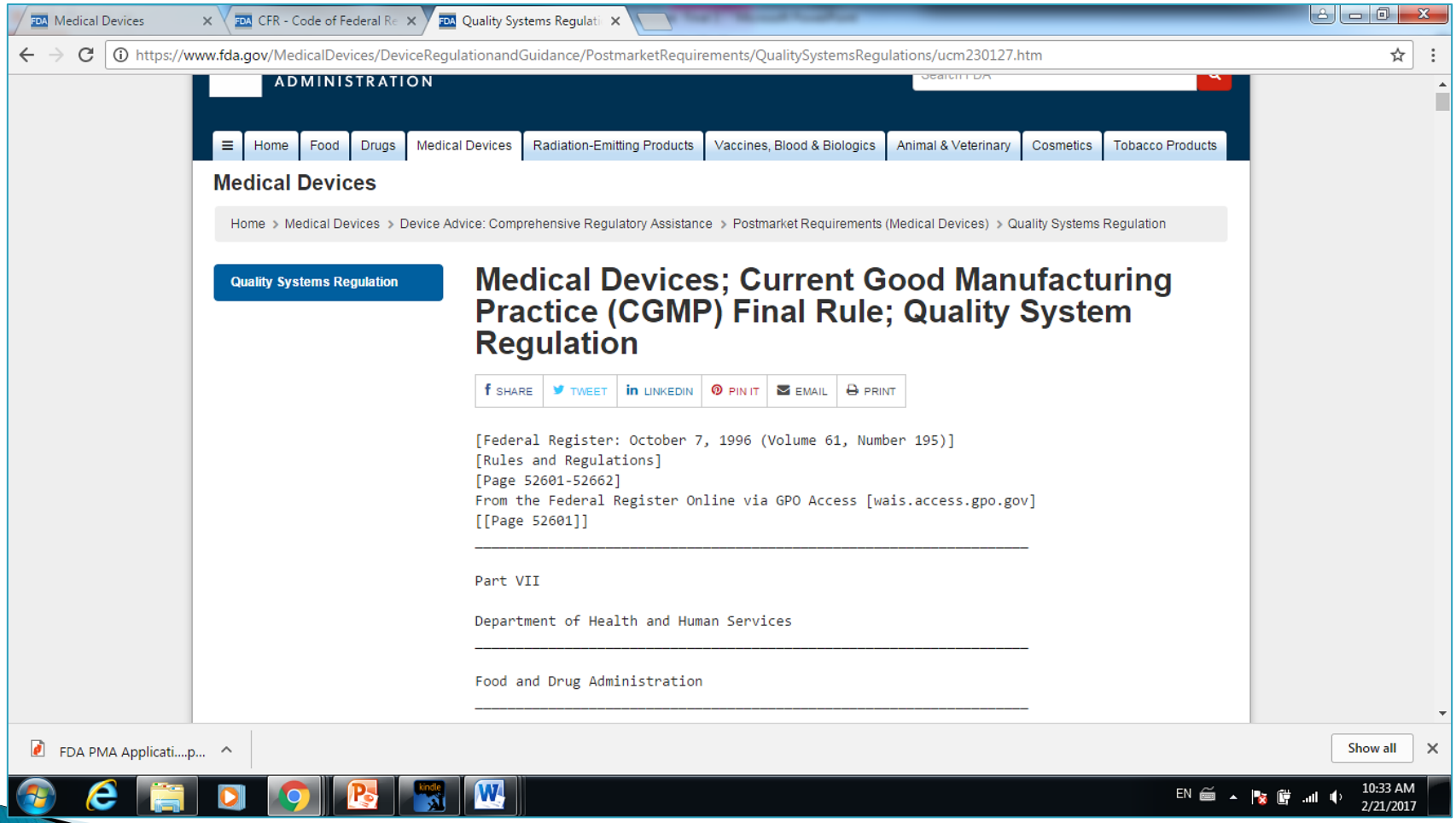
FDA Regulation of Medical Devices: Premarket Submission: De Novo

- De Novo:
- This premarket submission is a means by which a new device without a valid predicate can, if it meets certain criteria be classified as a class I or class II device.

Further Considerations

- Design Control:
- Required for all class II and class III devices. May be required for certain class I devices.
- The FDA document to consult for design control is that titled: Design Control Guidance for Medical Devices.
- The purpose of design control is: To ensure that good quality assurance practices are used for the design of medical devices and that they are consistent with quality system requirements worldwide
- The design control guidance document is provided by the FDA and relates to FDA 21CFR 820.30 and sub-clause 4.4 of ISO 9001.

Current GMP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Part VII
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Further Considerations

- Non Clinical Testing:
- The tests must comply with the FDA's Good Laboratory Practices (GLPs) in 21CFR 58.
- The required tests will depend on the device class, mechanism of operation and technological characteristics and labeling.

Further Considerations: Clinical Evidence

- Clinical Evidence:
- This is required for PMA, HDE, De Novo and some 510(k) devices.
- Prior to initiating a clinical study, an approval of an Investigational Device Exemption (IDE) by the FDA may be needed.

Further Considerations : Identification and Traceability

- GMP Subpart: F:Identification and Traceability
- Sec. 820.60 Identification
- Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups.

Further Considerations : Labeling and Packaging Control

- From GMP Subpart K: Labeling and Packaging Control
- Sec. 820.120 Device labeling
- Each manufacturer shall establish and maintain procedures to control labeling activities.
- Sec. 820.130 Device packaging.
- Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

Sterilized Medical Devices Must be Packaged According to GMP

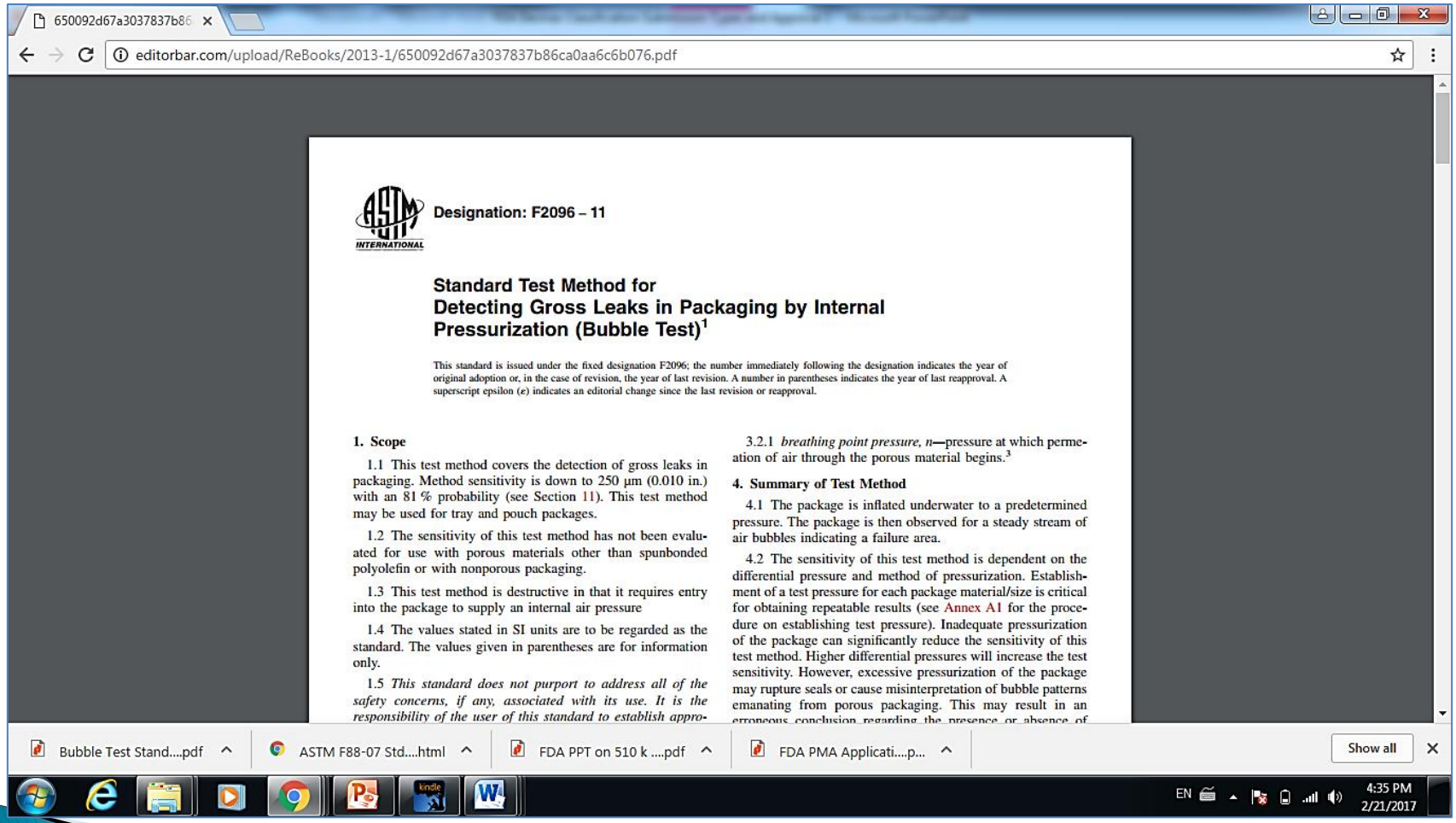
Further Considerations : Handling, Storage and Distribution

- From Subpart L: Handling, Storage, Distribution, and Installation
- Sec. 820.140 Handling.
- Each manufacturer shall establish and maintain procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

Further Considerations : Handling, Storage and Distribution

- Sec. 820.150 Storage.
- Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed.

An ASTM Standard Used to Validate FDA Packaging Requirement



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Designation: F2096 – 11

Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)[1]

This standard is issued under the fixed designation F2096; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers the detection of gross leaks in packaging. Method sensitivity is down to 250 µm (0.010 in.) with an 81 % probability (see Section 11). This test method may be used for tray and pouch packages.

1.2 The sensitivity of this test method has not been evaluated for use with porous materials other than spunbonded polyolefin or with nonporous packaging.

1.3 This test method is destructive in that it requires entry into the package to supply an internal air pressure

1.4 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appro-*

3.2.1 *breathing point pressure, n*—pressure at which permeation of air through the porous material begins.[3]

4. Summary of Test Method

4.1 The package is inflated underwater to a predetermined pressure. The package is then observed for a steady stream of air bubbles indicating a failure area.

4.2 The sensitivity of this test method is dependent on the differential pressure and method of pressurization. Establishment of a test pressure for each package material/size is critical for obtaining repeatable results (see Annex A1 for the procedure on establishing test pressure). Inadequate pressurization of the package can significantly reduce the sensitivity of this test method. Higher differential pressures will increase the test sensitivity. However, excessive pressurization of the package may rupture seals or cause misinterpretation of bubble patterns emanating from porous packaging. This may result in an

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Further Considerations : Handling, Storage and Distribution

- Sec. 820.160 Distribution.
- Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.
- The ASTM Tensile Strength Test, Bubble Test, and Accelerated Aging Test among others , are used to Verify and Validate these considerations.