Welcome to today's
FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

If you have not connected to the audio portion of the webinar, please do so now:

Dial: 888-790-3565

Passcode: CDRH

CDRH 510(k)Electronic Submission Pilot Program

Presenters

- **eSubmission Pilot overview**
  - Nelson Anderson
    Biomedical Engineer
    CDRH/ODE/DCD/VSDB

- **eSubmitter demonstration**
  - Patrick Axtell, Ph.D.
    Biomedical Engineer
    CDRH/ODE/POS

Overview

CDRH is conducting a pilot to evaluate a system that enables the

creation, submission, and review

of a 510(k) application through an entirely electronic process.

Eligibility

- **CDRH will be accepting 50 – 100 510(k)s in two branches of the Division of Cardiovascular Devices:**
  1. Cardiac Diagnostic Devices Branch
  2. Peripheral Interventional Devices Branch
- **Only unbundled*, traditional 510(k)s for classified devices are included.**
- **3rd Party, Special, or Abbreviated 510(k)s are outside the scope of this pilot.**

*Bundled submissions which contain multiple devices, each with a different product code(s) and/or indication(s) for use are not in the scope of this pilot

Device Types included

(This is not an exhaustive list.)

- Blood pressure monitors
- Implantable hemodynamic electrophysiology monitors
- Arrhythmia detectors
- Electrocardiograms
- Multiparameter monitors
- Diagnostic computers
- External defibrillation devices
- Diagnostic catheters
- Stents
- Atherectomy catheters
- Embolic protection devices
- Angioplasty catheters
- Embolectomy catheters
- Guidewires, introducers, guide/support/infusion catheters

Benefits of the Pilot Program

- **Client-side software (eSubmitter) that assists the applicant in creating the 510(k) submission.**
  - This software includes directions, advice, help text, and links to relevant guidance documents, regulations, and other resources.
- **Reduced transit time**
- **Lower expense:**
  - No printing/shipping costs for 510(k) submission as no hard copy is required
  - No electronic media costs (CDs, DVDs, or flash drives)

Benefits cont.

- **510(k)s submitted as part of the pilot program will not be subjected to the Refuse to Accept (RTA) checklist.**
  - All submissions that are within the scope of the pilot program, properly provide the requested documentation and data, and have paid the applicable user fee will be accepted.
- **May reduce the number of administrative questions asked by FDA reviewers as:**
  - all eSubmissions will have the same standard format
  - eSubmitter will not allow completion of a 510(k) submission when information is missing.

Pilot High-Level Process

Creation

- eSubmitter software assists in creation of 510(k) Submission
- Packages 510(k) submission for transport through ESG

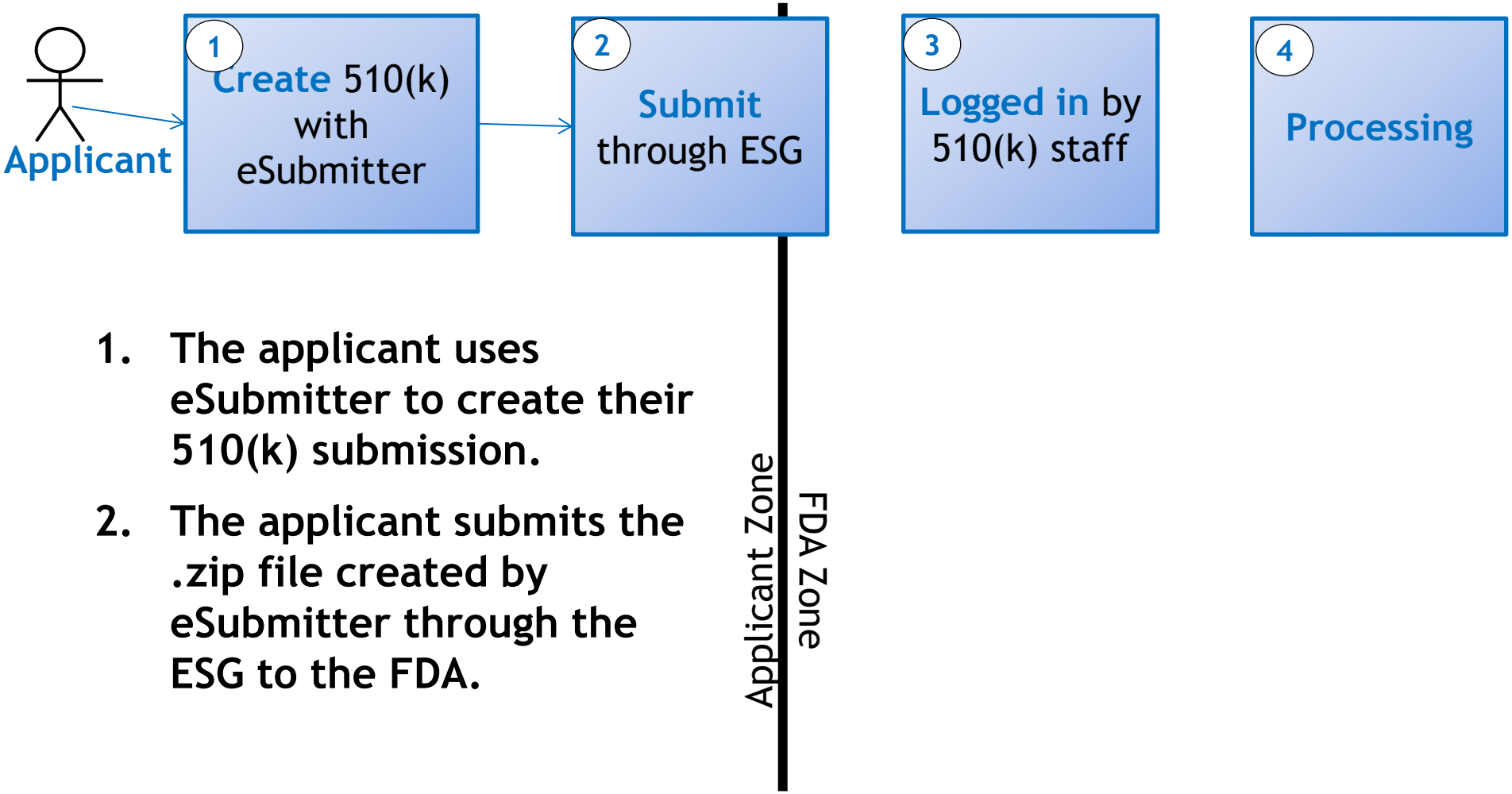
Submission

- The Electronic Submission Gateway (ESG) provides secure transmittal of the 510(k) package to CDRH/ODE

Review

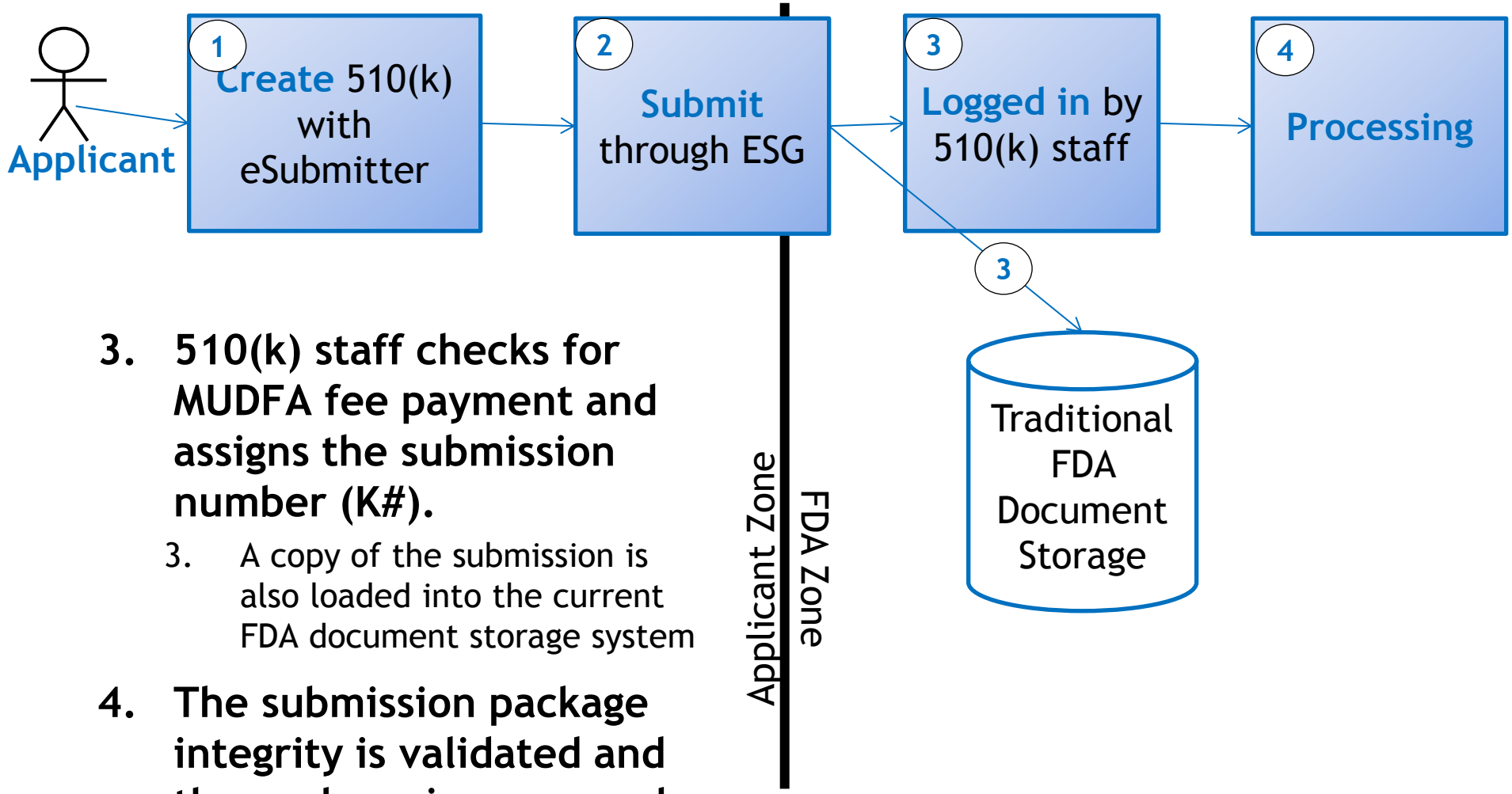
- On receipt of 510(k) package, it is logged in and processed
- ODE begins review of submission

Pilot Detailed Process



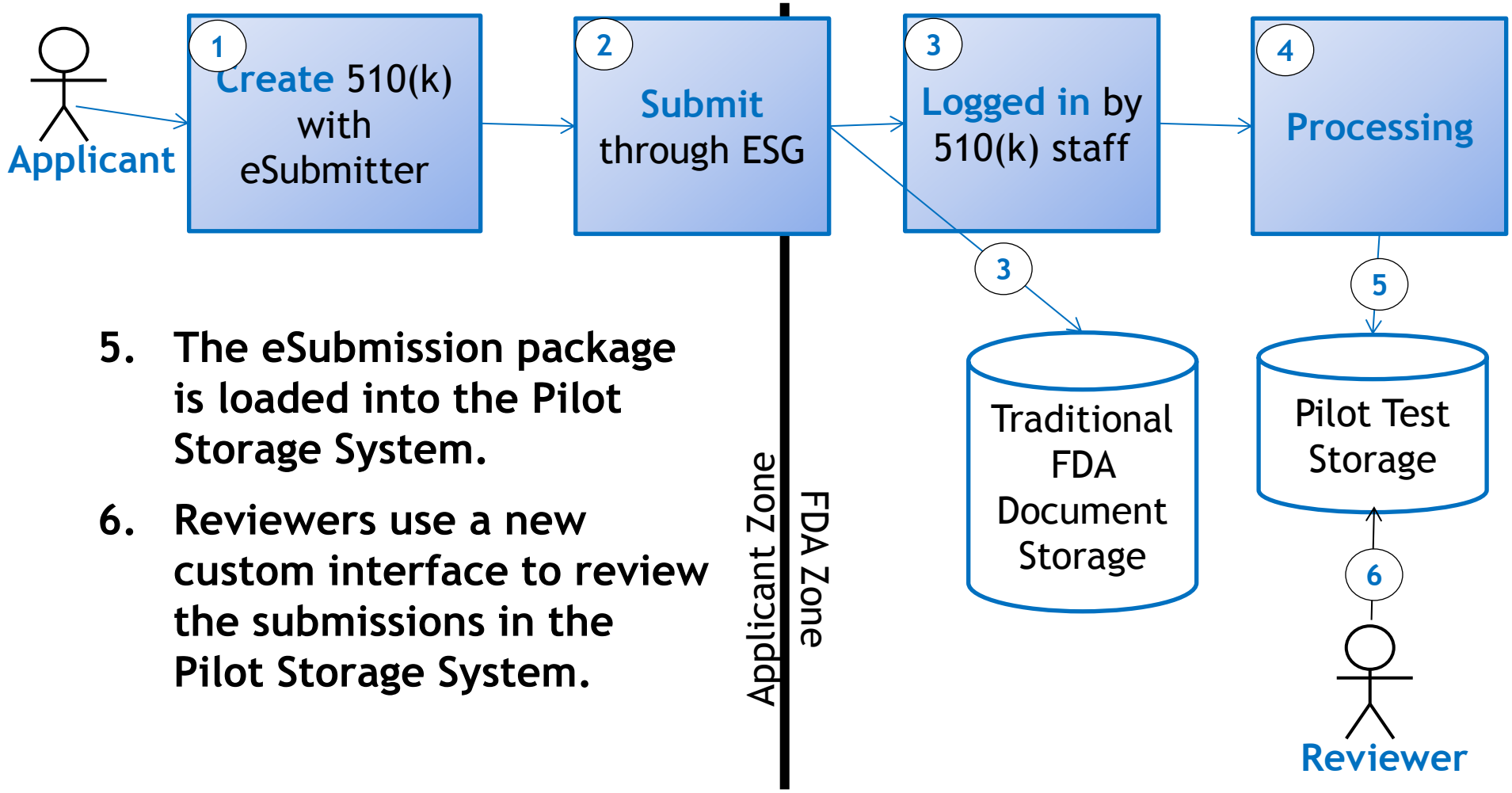
1. The applicant uses eSubmitter to create their 510(k) submission.
2. The applicant submits the .zip file created by eSubmitter through the ESG to the FDA.

Pilot Detailed Process



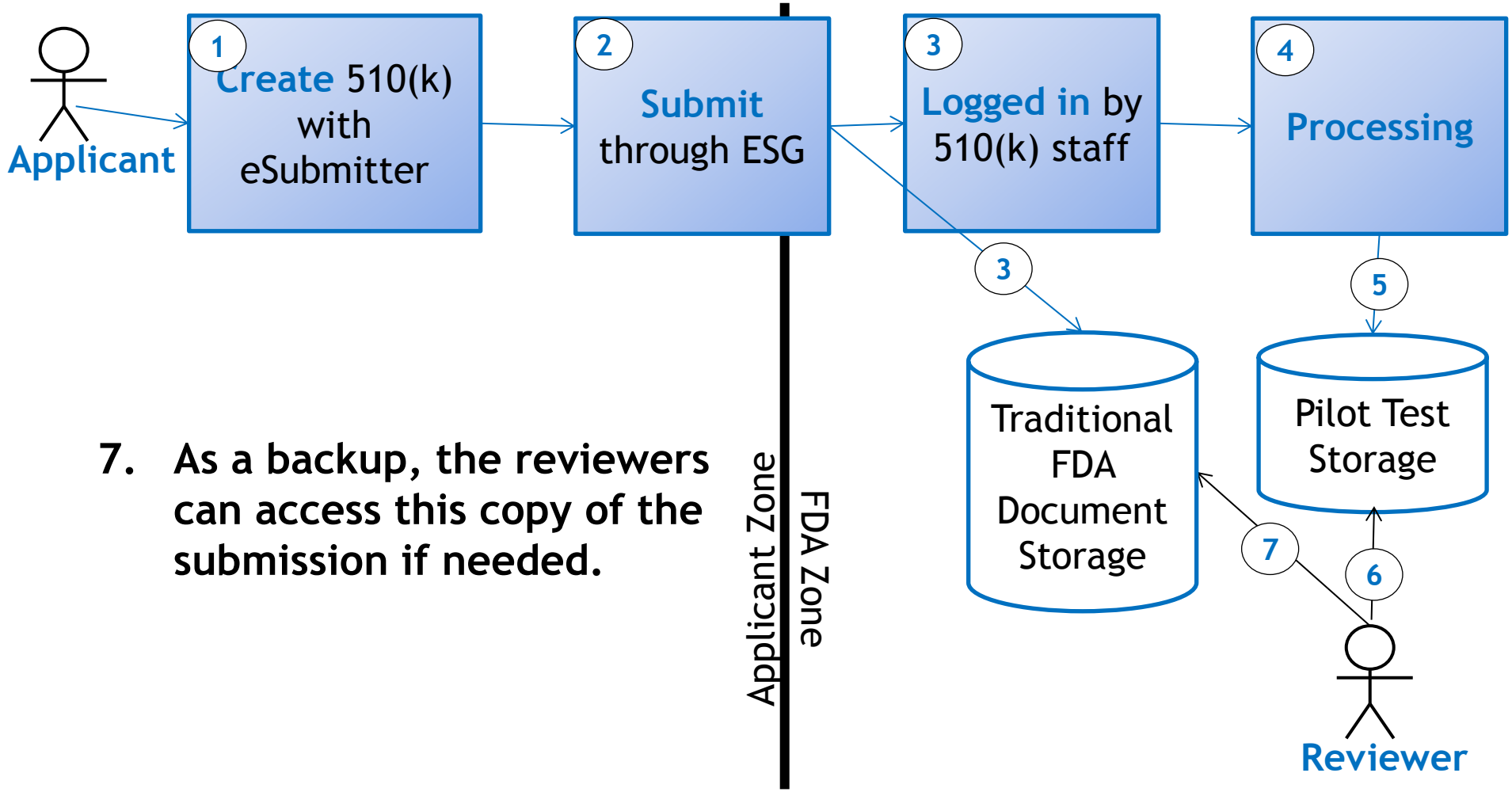
3. **510(k) staff checks for MUDFA fee payment and assigns the submission number (K#).**
   3. A copy of the submission is also loaded into the current FDA document storage system
4. **The submission package integrity is validated and the package is processed.**

Pilot Detailed Process



5. The eSubmission package is loaded into the Pilot Storage System.
6. Reviewers use a new custom interface to review the submissions in the Pilot Storage System.

Pilot Detailed Process



7. As a backup, the reviewers can access this copy of the submission if needed.

eSubmitter Software

- Is free to download from the FDA's website.
- Updates itself every time it is run, ensuring you have the latest version of the 510(k) template.
- Any interested companies, including those not participating in the pilot, can download the eSubmitter software with the 510(k) template and evaluate and provide feedback to CDRH.

FDA Gateway

- The Pilot will utilize the existing FDA Electronic Submissions Gateway (ESG).
- This is the same Gateway many companies already use to submit Electronic Medical Device Reports (eMDRs).
- Pilot participants who don't already have an ESG account can apply for one in order to participate.

FDA Gateway – Alternative

- For those who do not have sufficient technical resources or time to create a new ESG account, we have provided another option.
- MITRE has agreed to transmit 510(k) submission files on behalf of the applicant through their ESG account free of charge.
- MITRE has an NDA available to ensure confidentiality of the contents of a submission.
- For more information on this service please contact David Tanenbaum at cdrh_esubmissions@mitre.org.

For More Information

- **eSubmitter**
  - **General information :** http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm
  - **Download location:** http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm
  - **FAQs :** http://www.fda.gov/downloads/forindustry/fdaesubmitter/ucm306938.pdf
- **Electronic Submissions Gateway**
  - http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

For More Information

- **FDA eSubmission Pilot Website:**
  - http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm392813.htm
- **FR Notice**
  - https://www.federalregister.gov/articles/2014/05/01/2014-09912/center-for-devices-and-radiological-health-electronic-submission-of-premarket-notification

If you would like to participate in this pilot please contact us at: eSubPilot@fda.hhs.gov

eSubmitter 510(k) Template Demonstration

Questions?

eSubmission Questions: eSubPilot@fda.hhs.gov

Other CDRH Questions: CDRHQuestions@fda.hhs.gov **or** DICE@fda.hhs.gov

For more information on regulation of medical devices, visit *CDRH Learn* and *Device Advice* in the Medical Device section of FDA.gov