There are four basic steps involved in getting FDA marketing clearance in US:

1. Classify your device and understand applicable regulatory controls.
2. Select and prepare the correct Premarket Submission.
3. Send your Premarket Submission to the FDA and interact with the FDA staff during review.
4. Comply with Applicable Regulatory Controls Including the Establishment Registration and Device Listing

Note that most likely the device will fall under Class II of FDA and will require a 510(k) Premarket Notification submission for marketing clearance.

In step 2, the Premarket Submission must show that the device was developed and tested as follows:

- Design Controls: Class II and class III devices must be designed in accordance with Design Controls under the Quality System Regulation, 21 CFR 820.30.
- Non-clinical Testing: This includes performance verification testing, which is usually conducted by the manufacturer, and compliance verification to Safety and Electro-Magnetic Compatibility standards such as UL 60601-1 and 47 CFR 15b, which is conducted by an accredited laboratory.
- Clinical Evidence: Prior to initiating a clinical study, the study sponsor may need to obtain approval of an Investigational Device Exemption (IDE) by the FDA. The study will also need to be approved by the appropriate Institutional Review Board (IRB). Clinical studies must comply with all applicable IDE regulations and Good Clinical Practices (GCPs).
- Labeling: The labeling for a device must be written according to labeling regulations, 21 CFR 801.

Similar steps are involved in getting marketing clearance in EU:

1. Classify Your Device and Understand Applicable Regulatory Controls.
2. Prepare a Technical File or Design Dossier for Class III with evidence of compliance to the Medical Devices Directive.
3. Send Technical File to a Notified Body, interact with Notified Body staff during review and Receive a CE Mark certificate from if Class I with Measuring or Sterile function, Class IIa, IIb, or III.
4. Appoint a European Authorized Representative if you have no physical location in Europe and register the medical device with the Competent Authorities, where applicable.

Again most likely the device will fall under Class IIa.

In step 2, the Technical File will require that the device was developed and tested as follows:

- Design Controls: Medical devices must be designed in accordance with Design Controls under a Quality Management System certified to ISO13485.
- Non-clinical Testing: This includes performance verification testing, which is usually conducted by the manufacturer, and compliance verification to Safety and Electro-Magnetic Compatibility standards such as IEC60601-1 and IEC 60601-1-2, which is conducted by an accredited laboratory.
- Clinical Evidence: According to EN540 for clinical investigation.
- Labeling: Labeling is part of Safety standard.

Either exclude MDD or combine with FDA to keep slides clean.

The US and EU design controls standards are harmonized. Therefore developing a Quality Management System that complies to all is easy and prudent. Also the safety/EMC standards are harmonized for the most part. So testing against one holds for both. Hence the 10 basic steps to get to FDA (and EU) are:

1. Generate Design Requirements and a Development Plan
2. Design and develop the system and hold Design Reviews
3. Build prototypes and test
4. Perform Risk Analysis
5. Conduct design Verification including Safety/EMC testing and Software validation
6. Generate Design Output
7. Develop Manufacturing Processes and Validate
8. Manufacture Units for Clinical Trial
9. Prepare and conduct Design Validation via clinical trial
10. Prepare FDA submission and Technical File for EU submissions

Steps 2 to 5 may have to re-iterate.

We can figure out durations for each step to get a Gantt or a timeline but Artemis needs a Quality Assurance department along with Engineering.

https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device

https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k

TRADITIONAL 510(k) submission
Most companies must submit a traditional 510(k) Premarket Notification which is a full 510(k) that includes all of
the sections shown below:
1.
2.
3.
4.
5.
6.
7.
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9.
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11.
12.
13.
14.
15.
16.
17.
18.
19.
20.
21.

Medical Device User Fee Cover Sheet
CDRH Premarket Review Submission Cover Sheet
510(k) Cover Letter
Indications for Use Statement
510(k) Summary or 510(k) Statement
Truthful and Accuracy Statement
Summary and Certification
Financial Certification or Disclosure Statement
Declarations of Conformity and Summary Reports
Executive Summary
Device Description
Substantial Equivalence Discussion
Proposed Labeling
Sterilization and Shelf Life
Biocompatibility
Software

Electromagnetic Compatibility and Electrical Safety
Performance Testing ? Bench
Performance Testing ? Animal
Performance Testing ? Clinical

Applicant submits “informal” PMA Shell to the attention of the CDRH Branch Chief of the appropriate review division or to the applications division in the appropriate CBER office.
Applicant submits final PMA Shell to DMC or DCC
Applicant submits PMA modules in accordance with agreed upon schedule (each module subject to a 90-day review clock)
Applicant submits final PMA module, thereby completing the Modular PMA (180-day review clock)
Review division sends a letter to the applicant accepting the shell
Applicant submits user fee payment before 1st PMA module
Applicant reaches agreement with FDA

EN1441 Medical devices – risk analysis
EN980 Graphical Symbols for Use in the Labeling of Medical Devices 80/181/EEC
BS EN1041 Information supplied by the manufacturer with medical devices
BS EN540 Clinical investigation of medical devices for humans
IEC601-1-4 Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems

Any experimentation involving use of a medical device on a human subject falls under the IDE regulation and informed consent. If the medical device is a non-significant risk device, then FDA review of the IDE is not required - all you need is one hospital Institutional Review Board (IRB) to approve your clinical protocol and informed consent form, and you can conduct your study with oversight from the hospital IRB.