

Commercializing medical devices can be a complicated process. However, having a general understanding of the regulatory process in advance of commercialization can prove to be invaluable. Devices for which FDA approval is required include, but are not limited to, catheters, implantable materials or entire devices, imaging devices, diagnostic devices or other in-vitro diagnostics (IVD) and Health Apps.

If you believe you have a medical device that might have medical and commercial value based on initial prototype medical testing, what are the next steps you should take? INVO created this one-pager to help you better understand the premarket notification (PMN or 510(k)) application process with the FDA.

START THE PROCESS

As you are thinking about the regulatory process, contact the Innovations and New Ventures Office (invo.northwestern.edu) to assist you with issues related to intellectual property and potential commercialization. Some common initial questions that may arise are:

- Is there a patent? If so, who is the patent holder?
- What are your responsibilities as an inventor, physician, and/or a faculty member? What are NU's responsibilities?
- Have you explored potential areas for conflicts of interest? Contact the NU COI office (<http://www.northwestern.edu/coi>).

INVO staff may also be able to answer basic questions surrounding the regulatory process and working with the FDA.

IDENTIFY THE SPONSOR OF THE 510(k) APPLICATION

Determine whether the sponsor of the application is Northwestern, a corporate entity, the investigator, or another party. The sponsor defines the Manufacturer and is the liable party for FDA purposes.

CREATE A STRONG TEAM OF INVESTIGATORS

A successful 510(k) application requires a seasoned team: investigators (basic and/or clinical) who ideally possess knowledge of clinical testing under design control; research personnel; and knowledgeable individual(s) who can manage the administrative components of the 510(k) application and submission.

FAMILIARIZE YOURSELF WITH THE APPLICATION

Becoming knowledgeable about the application itself can help with achieving a complete and accepted application and ultimately, a 510(k) cleared device. The application needs to contain information in the following three broad areas.

1. Device Description

Determine the Class Identification (Class I, II or III) and Product Classification. Provide relevant Guidance Documents, Standards and Special control guidelines, as well as claims for Intended Use and Indications of Use. Identify whether it is a Device **only** or a Combination Device. State the type of submission and under which FDA Center the application should fall.

2. Substantial Equivalence Discussion

Identify at least one predicate device. Offer data that supports that the proposed device has some of the same or different technological characteristics as the predicate device. If necessary, include appropriate clinical or scientific data that demonstrates the device is as safe and efficacious as the predicate. Create a table comparing the proposed device and selected predicate devices, according to features, materials, and principles of operation.

3. Supporting Studies and Data

Overview of various studies and data to support general performance data or performance characteristics (for IVD only), shelf-life, biocompatibility studies, sterilization, labeling, software, and Electrical Safety, if applicable.

HELPFUL LINKS

- Northwestern [Innovation & New Ventures](#)
- Northwestern [Conflict of Interest Office](#)
- Access free [FDA Guidance Documents](#)
- Online FDA site to help identify [Predicate Devices](#)

PREPARE FOR THE PRE-SUBMISSION MEETING

This meeting provides guidance on the data needed to warrant 510(k) submission. It can save substantial time and effort. Be sure to address any concerns that are raised in this meeting and perform any additional studies requested or apply for a Request For Designation (RFD).

CONSIDER FILING AN IDE

If clinical studies are required to collect safety and effectiveness data, an application for an [Investigational Device Exemption \(IDE\)](#) and an [Institutional Review Board](#) approval might be warranted.

SUBMIT YOUR 510(K) APPLICATION

Construct and electronically submit your 510(k) application package per FDA guidance.