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PERSPECTIVE

Translational research of one dynamic hip screw system—from the SCI to the FDA

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Summary *Background/objective:* When researchers or developers wish to apply their findings to clinical usages, it must be approved by public authorities such as the US Food and Drug Administration (FDA). In addition to the development records and risk control documents, all of the materials and testing must be completed by laboratories or manufacturers with good quality controls in accordance with related regulations or standards. The Orthopaedic Device Research Center dynamic hip screw system (ODRC-DHS system), which was developed by the ODRC, National Yang-Ming University, Taipei, Taiwan, obtained FDA 510(k) clearance in 2011.
Methods: The application process was divided into five steps: (1) make sure that the product is a medical device and classify it; (2) find the predicate devices cleared by the FDA; (3) research any standards and/or guidance documents; (4) prepare the appropriate information for premarket submission to the FDA; and (5) send premarket submission to the FDA and interact with the FDA staff.
Results and Conclusion: The relevant regulations, guidelines, and strategies were detailed by step-by-step demonstration so that readers can quickly understand the requirements and know-how of a translational research.

Introduction

Many organizations use Science Citation Index (SCI) papers to assess the performance of researchers. However, engineers in undeveloped or developing countries could seldom read SCI papers due to language barriers or reading habits. This phenomenon means that the research results of these countries are unable to provide any substantial

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benefit to citizens. Therefore, translational research which not only profits the research team but also benefits the people has become very important.

To translate a research result into a legal medical device, additional evidence or documents are needed to ensure the quality and consistency of a product, such as the demonstration of contraindications, the approaches in reducing the risk, and the controls of production processes including manufacturing, cleaning, and sterilization. The requirements for a SCI paper and a medical device are summarized in Table 1.

A medical device is intended for use in saving or protecting the health of individuals, therefore it should not be used if the foreseeable risks clearly outweigh the benefits of use. For this reason, public authorities pay more attention to the risks and quality control of medical devices. They have set documents of regulations and/or guidance for medical devices, which must be fully complied with, to ensure the safety and effectiveness of devices [1—5]. The best strategy for preparing the submission of a medical device is to follow the available methods and the international standards and guidance documents. If existing regulations, standards or guidances cannot be found, it is possible that it is a new device and classed as Class III. Therefore, it may need to follow the premarket approval (PMA) submission process.

In different countries, the medical device classification and the required documents for license can be quite varied. The following introduction focused on the United States Food and Drug Administration (US FDA) criteria. Applicants can adopt the following steps prior to marketing a medical device in the US:

Step 1: Make sure that the product is a medical device and classify it.

Medical devices marketed in the US are subject to the regulatory controls in the Federal Food, Drug and Cosmetic Act (FD&C Act) [1] and the regulations in the Title 21- Code of Federal Regulations (21 CFR) Parts 1—58, 800—1299. According to the definition in Section 201(h) of the FD&C Act, a medical device is:

"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,
- 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, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve 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."

Many researchers believe that their products are medical devices, however, the products may not meet the above definitions. This will lead to unsuccessful licensing of the products. Medical devices are categorized into three classifications according to the risks of the devices by the US FDA as Class I, Class II and Class III (Table 2) according to Section 360c(a) of the FD&C Act [1]. The risks that a device poses to patients and the FDA regulatory control vary with the classifications. Medical devices in Class I typically possess simple designs and construction that present minimal potential harm to users with a history of safe use, so they should only comply with general controls. Medical devices in Class II are those whose sufficient safety and effectiveness cannot be assured by general controls, although the existing methods and the international standards and guidance documents are available to provide scientific evidences of safety and effectiveness. As well as complying with general controls, devices in this classification must conform to special controls. Premarket notification, i.e., submission and the FDA review of a 510(k) clearance, is required for the legal marketing of some Class I devices, nearly all Class II devices, and a very small number of Class III devices. Class III devices are usually used for supporting or sustaining human's life, or preventing a potential unreasonable risk of illness or injury in patients. The most stringent regulatory controls are set for Class III medical devices because the information provided by general controls and special controls is insufficient to assure safety and effectiveness. Typically, a PMA submission to the FDA is required in order to market a Class III medical device.

Table 1 General Requirements for SCI papers and medical devices.

	SCI paper	Medical device
Indications[a]	Yes	Yes
Contraindications[b]	No	Yes
Effectiveness	Yes	Yes
Safety	No	Yes
Quality system	No	Yes

SCI = Science Citation Index.
[a] Indications denote the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the target patient population.
[b] Contraindications denote when the device should not be used.

Table 2 FDA medical device classifications.

Classifications [a]	Risk	Level of regulatory control
Class I	Minimal	General controls
Class II	Medium	General controls and special controls (510k)
Class III	High	General controls and PMA

FDA = Food and Drug Administration; PMA = premarket approval.
[a] The classifications are according to Section 360c(a) of the FD&C Act [1].