Who Owns the 510(k)?

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Unfortunately, some medical device manufacturers, particularly those based outside the United States (US) are unaware of the business implications of submitting a 510(k) premarket notification to the US Food and Drug Administration. This article discusses information regarding the ownership and other business related aspects of filing a 510(k).

Image: Digital Vision

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Mistaken beliefs

Recently, a medical device manufacturer located outside the United States (US) mistakenly believed that only someone in the US was able to submit a premarket notification, otherwise known as a 510(k), on his behalf. As a result, the manufacturer agreed to have a US distributor submit the 510(k) to the US Food and Drug Administration (FDA). It was only after the submission was filed that the manufacturer realised that he could have submitted the 510(k) directly to FDA or requested that the US distributor specify that the manufacturer was the applicant and owner of the 510(k). This mistaken belief led to significant financial consequences for the manufacturer because of agreements that had to be made with the distributor who owned the 510(k).

Unfortunately, some companies, both in and outside the US, continue to believe that only entities residing in the US can file a 510(k). This can lead to nonUS medical device manufacturers unnecessarily ceding the ownership of a 510(k) to the party that submits the 510(k) to FDA. This misconception may be due in part to a section in the Medical Device Reporting (MDR) regulation (21 Code of Federal Regulations (CFR) Part 803). Section 803.58, Foreign Manufacturers, requires that nonUS manufacturers designate a US agent to be responsible for reporting under the MDR regulation and also registering, listing and submitting premarket notifications in accordance with 21 CFR 807. However, an Effective Date Note located at the end of the section specifies that the requirements of section 803.58 have been postponed indefinitely. Unfortunately, the note is not always seen or understood and, therefore, can lead to the mistaken belief that only US designated agents can submit premarket notifications for nonUS manufacturers.

Current requirements

The requirements currently in force regarding the need to designate a US agent are in section 807.40 of 21 CFR 807. This regulation requires nonUS establishments engaged in manufacturing and other activities to register with FDA and designate a US agent. The primary responsibility of this US agent is to assist FDA with communications with the nonUS establishment, respond to questions concerning the products that are imported into the US, and assist in scheduling FDA inspections of the nonUS establishment. The duties of a US agent under current regulations no longer include those listed in section 803.58, including the submission of premarket notifications. Thus, nonUS manufacturers are not obliged to ask a US entity to file a 510(k).

To make fully informed decisions regarding who will submit a 510(k), all parties must understand that nonUS companies, including nonUS manufacturers, may submit a 510(k) directly to FDA. Alternatively, if they request that the 510(k) is filed by an entity in the US, nonUS manufacturers can retain ownership of the 510(k), providing this is specified in the 510(k) submission. As stated on the FDA Device Advice website (www.fda.gov/cdrh/devadvice), a nonUS manufacturer may receive assistance from a US entity and may use a contact person residing in the US; however, this is not a requirement for a 510(k) submission.

For example, nonUS manufacturers sometimes request a US distributor to file a 510(k) with the full knowledge that →

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→ the distributor will own the 510(k) unless specified otherwise; the manufacturer makes this decision based on financial agreements with the distributor. In other cases, nonUS manufacturers request that their US agent or other external experts develop and/or submit a 510(k) on their behalf because the nonUS manufacturers do not believe that they have the requisite knowledge to do this.

Clear specification of ownership

A company wishing to market a medical device in the US that requires the submission of a 510(k) should review the FDA document: Format for Traditional and Abbreviated 510(k)s,[1] regardless of whether or not the company plans to submit the 510(k), or have this done by another entity. The document provides guidance on how to format an original submission for a traditional or abbreviated 510(k). It also contains crucial information on how FDA identifies the owner of a 510(k).

The FDA guidance document defines the "510(k) submitter/holder" as the owner of the 510(k). It also states that although a consultant or correspondent may submit the 510(k) on behalf of the 510(k) owner, that consultant or correspondent is not the 510(k) submitter/holder.

The document also includes information on the inclusion in the 510(k) of a voluntary form, the Center for Devices and Radiological Health's Premarket Review Submission Cover Sheet. An advantage of including this form in a 510(k) is that it provides a means for clearly identifying the submitter or applicant, that is, the owner of the 510(k), from the application correspondent, if that entity is different from the submitter or applicant. The correspondent could be someone in another company who is submitting the 510(k) to FDA on behalf of the submitter or applicant or a consultant. A link to the form is included in the FDA guidance document (www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf). Companies that have engaged an external party to prepare the 510(k), but wish to retain ownership of the 510(k) should review the entire 510(k) before it is submitted and should ensure that the Cover Sheet, if included, is completed correctly to indicate the agreed arrangements between the preparer and owner of the 510(k).

When two 510(K)s are required for the same device

In some cases, the need to submit a 510(k) is affected by the business arrangements of various parties who manufacture, market or distribute the same medical device.

A US distributor submitted a 510(k) for a device manufactured by a nonUS contract manufacturer, Company A, and marketed the device with a commercial name chosen by that US distributor. Company B, which owned the contract manufacturer, manufactured the same device and marketed it with another commercial name outside the US, wished to market the device in the US. The device had identical specifications and was made of the same materials. In this case, is it possible for Company B to market the device in the US under the 510(k) that was submitted by the distributor?

The answer is "no" because Company B is seeking to manufacture the device for introduction in the US under its own name. In this case, the CFR section that applies is 807.81(a)(2), When a Premarket Notification Submission is Required. This specifies that a premarket notification is required at least 90 days before introduction or delivery for introduction into US interstate commerce, if various criteria are met. One of the criteria, listed in paragraph (a)(2) is that the device is being introduced into commercial distribution for the first time by a person required to register. Therefore, Company B must submit a 510(k) to FDA regardless of the fact that the device is identical to the device already on the market under a previous 510(k). It is also not relevant that the distributor would have allowed Company B to use the already cleared 510(k).

Conversely, a nonUS manufacturer who has filed a 510(k) for a particular device can sell the product to any number of US distributors and none of them would need to file a 510(k). This is because section 807.85(b), Exemption from Premarket Notifications, applies. This section states that a distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labelling or otherwise affect the device, shall be exempted from the premarket notification requirements if

- the device was in commercial distribution before 28 May 1976, or
- a premarket notification submission was filed by another person.

Transfer of 510(k) ownership

A nonUS medical device manufacturer, Company X, submitted a 510(k) for a medical device that was marketed in the US. The owner of the company decided to close the company and founded Company Y, which was also outside the US. Can the owner of Company X transfer the ownership of the 510(k) to Company Y?

The answer is "yes." It is common practice for companies to sell products that have 510(k)s to other companies. For example, a company receives 510(k) clearance for a medical device and then sells the device and ownership of the 510(k) to another company, which produces the device for a period of time and then goes out of business. A third company purchases the 510(k) from creditors and resumes production of the device. However, the name of the applicant in the FDA 510(k) database, which is accessible on the FDA website (www.fda.gov/cdrh), and the posted Summary of Safety and Effectiveness are not changed by FDA when ownership changes. It should be noted that there is no requirement to notify FDA of changes of ownership.

Whenever a company purchases a 510(k), it is important that records of the transaction are maintained to show, in case of a FDA quality system inspection or questions from customers or others, that the company is the legal owner of the 510(k) and that the device is being produced under essentially the same specifications and controls as those covered by the original 510(k). Using the example above,

FDA advises that device import entry documents include the 510(k) number of the product and a statement that "510(k) number submitted by Company X was transferred to Company Y on [date of transaction]."

Business transfers such as these can sometimes lead to delays at a US port of entry for the product because a local FDA import district may believe that a company is illegally using another company's valid 510(k), perhaps obtained from the FDA database, for the same type of device. The risks of this type of delay may be reduced if entry documents clearly show that if customs officials check a particular 510(k) number, they will find that another company was the submitter of the 510(k).

Reference

1. Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s, FDA, Center for Devices and Radiological Health, Office of Device Evaluation and Office of In Vitro Diagnostic Device Evaluation and Safety, 12 August 2005. Downloadable from www.fda.gov/cdrh/ode/guidance/1567.pdf mdt

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