

How to Transfer Ownership of a 510(k) Clearance or PMA Approval

Many medical devices require 510(k) clearance or premarket application (PMA) approval from FDA prior to commercial distribution. A firm that is purchasing or licensing medical device technology already on the market needs to make certain that the deal also includes a valid transfer of the 510(k) clearance or PMA approval to assure that commercial distribution can be lawfully continued. The FDC Act and implementing regulations are silent on such transfers. However, historically, FDA has permitted them.

Premarket Review of Medical Devices

It is helpful to review the regulatory scheme for the premarket review of medical devices. Devices classified by FDA as posing less risk are placed in Class I or Class II and, unless exempt, the manufacturer is required to seek "510(k) clearance" prior to marketing. This clearance is granted pursuant to the premarket notification provisions of Section 510(k) of the FDC Act. It generally is granted when submitted information establishes that a proposed device is "substantially equivalent" in intended use and safety and effectiveness to a legally marketed device already granted 510(k) clearance. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in the intended use, requires a new 510(k) submission. The manufacturer is responsible for determining whether a device modification requires a new 510(k) submission.

However, FDA may disagree retroactively with a manufacturer's determination not to seek 510(k) clearance for one or more device modifications and retroactively require submission of a new 510(k) notification. In a worst case scenario, FDA could halt commercial distribution of the modified device until the new 510(k) notice is cleared.

A device that does not qualify for 510(k) clearance is placed in Class III, which is reserved for devices classified by FDA as posing the greatest risk. A Class III device

generally must undergo the PMA approval process, which requires the manufacturer to prove the safety and effectiveness of the device to FDA's satisfaction in a rigorous scientific review. After PMA approval, a PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process affecting the safety or effectiveness of the device.

Transfer of 510(k) Clearance

FDA does not have a written policy on transferring ownership of a 510(k) clearance. Nonetheless, FDA permits such transfers, with the important caveat that two companies may not manufacture the same device under a single 510(k) clearance. Therefore, if a 510(k) holder wishes to license the right to manufacture a device but also wishes to continue its own manufacturing activity, FDA's policy is to require the licensee to obtain a new 510(k) clearance. Because of this policy, it is advisable for the buyer to obtain an agreement from the seller to cease manufacturing after transfer of the 510(k) clearance. Furthermore, the agreement should transfer the 510(k) clearance to the buyer on an exclusive basis. A non-exclusive transfer of 510(k) clearance creates a risk in that the buyer will be required to obtain a new 510(k) clearance if another party is manufacturing under the same clearance number.

FDA does not record 510(k) transfers as such. Thus, it is not necessary to notify FDA about the transfer of a 510(k) clearance (although the new 510(k) holder will be required to file device listing form FD-2892, which will list the transferred device under its name). Because FDA does not track 510(k) transfers, it is possible for an unscrupulous firm (or an incompetent one) to sell its 510(k) clearance more than once. Therefore, it is advisable to obtain a warranty that the seller owns the 510(k) clearance and has not previously transferred it to any other party.

The issue of submitting a new 510(k) for device modifications is pertinent to a 510(k) transfer in two ways. First, there is the question of whether the transfer of the device and/or 510(k) clearance requires a new 510(k) submission. FDA generally does not consider either of these transfers as necessarily requiring a new 510(k) submission. Even if the device will be manufactured at a new site, FDA's position is that a new 510(k) is not required unless the site change could significantly

DEVICES CLASSIFIED BY FDA AS POSING LESS RISK ARE PLACED IN CLASS I OR CLASS II AND, UNLESS EXEMPT, THE MANUFACTURER IS REQUIRED TO SEEK "510(K) CLEARANCE" FROM FDA PRIOR TO MARKETING. THIS TYPE OF CLEARANCE IS GRANTED PURSUANT TO THE PRE-MARKET NOTIFICATION PROVISIONS OF SECTION 510(K) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (FDC ACT).

affect the safety or effectiveness of the device. (This is not true for Class III devices approved through the PMA approval process where a change in manufacturing site automatically requires the filing of a PMA supplement.)

Second, because a 510(k) clearance is based upon a specific device, it is essential that the device described in the transfer agreement match the device described in the 510(k) clearance. This determination is not as straightforward as one might expect. The 510(k) holder may have modified the device after clearance without submitting a new 510(k) notice by concluding the changes could not significantly affect safety or effectiveness. It is therefore possible that the existing 510(k) clearance is not legally sufficient to allow commercial distribution of the device the buyer is purchasing. To assess this risk, the 510(k) buyer should obtain a list of all modifications and assess whether the 510(k) holder's "no file" decisions were reasonable. In addition, it is desirable for the buyer to obtain a warranty that the existing 510(k) clearance is legally adequate for the device as currently manufactured and distributed, taking into account all modifications to the device after clearance. Otherwise, the buyer should be prepared to accept the risk that a new 510(k) notice will be required for post-clearance modifications.

Transfer of PMA Approval

FDA's 1986 PMA Manual (reprinted August 1989) sets procedures for transferring PMA ownership and for licensing PMA-approved device technology. Oddly, the revised version of the manual (published in January 1998 and available on the CDRH Web site (www.fda.gov/cdrh) omits these procedures. Discussions with FDA staff indicate that this omission was inadvertent. It also does not have legal significance, because the manual is not a regulation, but simply a compendium of FDA policies and procedures intended to assist the public in understanding the PMA requirements. Thus, it appears that the procedures for transferring ownership and licensing remain the same despite the omission.

Change of Ownership

Ownership of a PMA may be transferred before or after approval. At the time of transfer, the transferor should provide an original and a copy of a letter notifying FDA that all rights to the PMA have been transferred to the new owner.

The ownership transfer will not result in a new PMA number being issued to the new owner. If the

PMA has been approved, the new owner need only report that the transfer will not result in a change or modification that would require a PMA supplement or affect the conditions of approval applicable to the PMA in question. Otherwise, the new owner must submit an appropriate PMA supplement (pursuant to 21 C.F.R. § 814.39) and obtain written FDA approval before marketing the device.

The report of transfer or PMA supplement must: (i) notify FDA of the effective date of the transfer; (ii) contain a statement of the new owner's commitment to comply with all applicable conditions of approval; and (iii) provide either a statement that the new owner has a complete copy of the PMA (including all amendments, supplements and reports) or a request for a copy from FDA's files.

If the transfer occurs before the PMA is approved, the PMA must be amended to include the information and ownership transfer letter described above.

Licensing

When the holder of an approved PMA enters into an agreement to permit another firm to manufacture and distribute a device under the licensee's private label, FDA approval may be obtained by either of two procedures: (i) the PMA holder may submit a supplement to the approved PMA; or (ii) the licensee may submit an original PMA that includes, or includes by authorized reference to the holder's approved PMA, all appropriate information required by 21 C.F.R. § 814.20 (required information for PMA applications). Multiple licensees are permitted provided the appropriate FDA approval is obtained for each license.

The advantage of the first procedure is that it may be faster. It was significantly faster when the second procedure required FDA to publish notice of an approval decision in the *Federal Register*, which sometimes took a year or more. Now that FDA publishes approval decisions on its Web site fairly promptly, the time advantage of the first procedure has been diminished.

The advantage of the second procedure is that, after approval, the original PMA holder may not rescind any authorization permitting the licensee's use of information in the original approved PMA. The licensee also may use that same information in support of changes or modifications later proposed by the licensee. In short, the licensee gains control of the PMA approval independent of the original PMA holder.

Under either, a PMA submission must include:

- a statement signed by both parties confirming the

original PMA holder furnished the licensee with a complete copy of all manufacturing data in the approved PMA applicable to the manufacture of the device;

- a complete description of the licensee's manufacturing facilities and a listing and explanation of all differences between the original PMA holder's and the licensee's methods and controls used in the manufacture and distribution of the device;
- process validation and expiration date information, where appropriate;
- copies of all required labeling (draft or final) and a description of all differences between the PMA holder's and the licensee's labeling;
- a description and results of all tests and evaluations demonstrating that the licensee's device is identical or sufficiently similar to provide reasonable assurance that the licensee's device is safe and effective; and
- the licensee's FDA establishment registration number, and, if applicable, the dates of the most recent FDA inspection of the licensee's manufacturing facility.

© 2000 by the Regulatory Affairs Professionals Society (RAPS). Posted with permission on www.hhlaw.com. Reprinted from the April 2000 issue of *Regulatory Affairs Focus*. This article may not be published, reposted or redistributed without express permission from RAPS and payment of appropriate fees when applicable. To obtain such permission, send a message to acrompton@raps.org.

Transfer of Records

There are various record keeping requirements that apply to device manufacturers, including maintaining complaint files, reports of adverse events, reports of corrections and removals, device master records (DMRs), device history records and quality system records (See generally 21 C.F.R. Parts 803, 806, 820).

Of particular importance are the DMRs, which contain device specifications, production process specifications, quality assurance procedures and specifications, packaging and labeling specifications, and installation, maintenance, and servicing procedures (See 21 C.F.R. § 820.181). A transfer of either 510(k) clearance or PMA approval should include an agreement by the owner to transfer the DMRs and all other records generated pursuant to FDA's regulations that are necessary to assure that the buyer can continue to manufacture and distribute the transferred device in compliance with FDA's regulations.

Jeffrey K. Shapiro is a partner specializing in medical device law and regulation at Hogan & Hartson, Washington DC. His email address is jkshapiro@hhlaw.com.