CERTIFIED MAIL

2094 '01 MAR 12 P2:46

March 7, 2001

ARROW INTERNATIONAL

2400 Bernville Road
Reading, PA 19605 USA

(610) 478-3137
FAX: (610) 478-3172

e-mail: tom_nickel@arrowintl.com
www.arrowintl.com

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 00N-1625 – Medical Devices: Rescission of Substantially Equivalent Decisions and Rescission Appeal Procedure – Proposed rule

Dear Sir or Madam:

It is not unreasonable for FDA to define by regulation the procedure by which 510(k) substantial equivalence decisions are rescinded because new information has become available which conclusively proves the device in question is not as safe and effective as the legally marketed predicate device.

The proposed regulation exceeds this reasonable objective in that several of the grounds for rescission are so open-ended and non-specific as to make them easily subject to agency abuse. In addition, the administrative review procedure afforded the 510(k) holder is unacceptable as written because the opportunity for an erroneous identification of the 510(k) holder is probable, given FDA's lack of an adequate database of 510(k) holders. Further discussion follows.

Criteria for rescission

The proposed regulation lists 6 criteria for rescission. Our comments on each follow.

Criterion 1

"(1) The premarket notification does not satisfy the criteria under §807.100(b)(1) or (b)(2) for a determination of substantial equivalence."

Comment

Acceptable as written.

00N-1625 C3

Criterion 2

"(2) Based on new safety or effectiveness information, the device is not substantially equivalent to a legally marketed device."

Comment

This statement is basically a statement generalizing the other 5, and should be deleted as overly vague and redundant.

Criterion 3

"(3) (i) FDA or the 510(k) holder has removed from the market, for safety and effectiveness reasons, one or more legally marketed device(s) on which the substantial equivalence determination was based, or
(ii) A court has issued a judicial order determining the legally marketed device(s) on which the substantial equivalence determination was based to be misbranded or adulterated."

Comment

This is overly broad and non-specific, and would allow rescission of a 510(k) if an overzealous FDA individual were to determine that the predicate device for a 510(k) substantial equivalence decision had been removed from the market for any safety or effectiveness reason whatsoever, regardless of whether the reason is pertinent to the device in question.

Additionally, a judicial order determining a predicate device to be misbranded or adulterated is unreasonable as a criterion (as stated) for rescission unless it is proven that the particular misbranding or adulteration concern is directly applicable to the device for which the 510(k) rescission is being considered.

Criterion 4

"(4) The premarket notification contained or was accompanied by an untrue statement of material fact."

Comment

This statement almost begs for abuse. An unintentional inaccurate statement in a 510(k) could lead to rescission. This should be rewritten to reflect purposely untrue statements of material fact intended to facilitate the original finding of substantial equivalence.

Criterion 5

"(5) The premarket notification included or should have included information about clinical studies and these clinical studies failed to comply with applicable institutional review board regulations (part 56 of this chapter) or informed consent regulations (part 50 of this chapter) in a way that the rights or safety of human subjects were not adequately protected."

Comment

A finding that a clinical study had a technical deficiency regarding IRB approval or informed consent long after a 510(k) substantial equivalence decision is rendered on a device is not sufficient reason to assume the decision was incorrect. The exact nature of the perceived deficiency and its relevance to the substantial equivalence decision would have to be studied in some detail to make this determination. As with the previous concerns, this criterion for rescission is excessively broad as stated and begs for abuse.

Criterion 6

"(6) The premarket notification contained clinical data submitted by a clinical investigator who has been disqualified under §812.119 of this chapter."

Comment

Once again, the lack of detail makes this criterion for rescission unreasonable and unacceptable. If only one investigator was involved and the nature of the disqualification was such that the data generated by the study were in question regarding safety and effectiveness of the device, no problem. However, (6) does not say that, and so the lack of specificity makes the criterion for rescission unworkable.

Notice of proposed rescission and opportunity for a hearing

This section is unacceptable in that it does not adequately protect the 510(k) holder from an inappropriate rescission action by FDA. The problem relates to the definitions and the reality of the information FDA has in its database.

The problem is with "the 510(k) holder of record," as defined in the proposed regulation. **FDA only has record of the organization originally submitting a 510(k) to CDRH.** Ownership of 510(k) submission is commonly transferred from one organization to another in acquisitions and other similar changes in interests between companies, importers, distributors, etc.

As an example, we have acquired ownership of numerous 510(k)s in 5 different product line acquisitions from other manufacturers over the last 14 years. We have notified CDRH of the details of each, including a list of the specific 510(k)s involved, and have been advised in writing for the most recent notifications that CDRH does not keep track of 510(k) ownership changes, and that this information should be documented by us only for FDA field inspection purposes.

Therefore, when FDA notifies a 510(k) holder of record of a proposed rescission, it is likely they will not respond, and the rescission will be effected anyway. The only way the 510(k) holder would be aware of this is if they check the CDRH Internet home page daily. This is an entirely unacceptable method of notification.

While we understand your desire to formalize the 510(k) rescission process, the proposed regulation requires considerable rework before it is a practicable, abuse-resistant procedure which protects both the public health and the rights of the 510(k) holder.

Sincerely,

Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

2001021ltr

ARROW
INTERNATIONAL

P.O. Box 12888
Reading, PA 19612

7099 3400 0010 0084 6692

CERTIFIED MAIL

PLACE STICKER AT TOP OF ENVELOPE
TO THE RIGHT OF RETURN ADDRESS.
FOLD AT DOTTED LINE

READING
MAR07'01
PA

U.S. POSTAGE
03.95
H METER 700094

Dockets management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

20857-0001