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March 6, 2001

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

Re: [Docket No. 00N-1625] Proposed Rule - Medical Devices; Rescission of Substantially Equivalent Decisions and Rescission Appeal Procedures

Dear Sir or Madam:

Attached are general comments regarding the overall thrust of the proposed rule and specific comments regarding sections within it. Please include these comments in your review of the responses that you receive from the public regarding this proposal.

As you will note in the attached comments, Zimmer, Inc. is strongly opposed to the adoption of the proposed rule Thank you for considering these comments as you go through the formal "notice and comment" requirements for rule making.

Sincerely,

T. M. Wendt, Ph.D.
Vice President, Regulatory
Affairs and Compliance

00N-1625

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Comments Regarding
Proposed Rule

"Medical Devices; Rescission of Substantially Equivalent
Decisions and Rescission Appeal Procedures"
Docket No. 00N-1625

General Comments:

1. The general thrust of the proposed rule appears to be directed at the removal of specific devices, which for a variety of reasons appear to pose a threat to public health. However, the mechanism by which the action is taken has the effect of modifying the class of an entire range of products, moving them from a lower risk class to a higher risk class. For instance, rescission of a 510(k) for device that has been cited by other devices as one of a group of predicate devices, places the entire group of devices at risk for rescission. If rescission of a predicate in effect invalidated the submissions claiming it as a predicate and there were no other predicate to which substantial equivalence could be established, the effect would be a change in class for the entire group of devices so affected. The established procedures for determining the class of medical devices should not be circumvented by application of a new rule such as could be the case here.

2. The statement by the FDA that this regulatory option does not have a significant economic impact on a substantial number of small entities does not appear to take into account the potential far-reaching consequences of the rescission of a single device decision. The statement that the FDA has proposed only five rescissions from 1997 through 1999 and only one up to May of 2000 has no bearing on the potential application of the proposed rule. The effect of the proposed rule would appear to make the rescission of 510(k) clearance decisions much easier to effect than has previously been the case. How this would be used by the Agency is problematic and has the overall effect of greatly lessening the predictability of market availability of groups of medical devices. This would be unacceptable from a business perspective, whether the commercial entity was large or small. However, and more to the point, there is potential for serious disruption of the flow of devices necessary for the treatment of patients.

3. The FDA acknowledges in the proposal that their information on the actual holder of a 510(k) may not be accurate or up to date. To ensure the information of a proposed rescission reaching the holder of the submission, they propose widespread public disclosure of the intention for rescission without specifying reasons. The use of such public notice prior to the opportunity to contest the rescission action has potential to do extensive economic damage to the company or companies involved. This aspect of the proposed rule is unacceptable. Other means of communication with holders of

510(k)s exist and should be employed in preference to the proposed means with its implication of wrongdoing prior to opportunity to dispute the findings of the Agency.

Specific Comments:

1. Six bases for proposing rescission of a 510(k) substantial equivalence (SE) decision are listed in the proposed rule. Numbers one and two appear to open the door to general policy shifts within the Agency in a manner that the proposed rule would allow to be retroactive. The test that ought always to be applied to existing devices is whether there is evidence that they are performing in a safe and effective manner for their intended uses. If that test is passed for an existing range of devices, the fact that the FDA has decided to impose additional new or different requirements should not affect the market status of those existing safe and effective devices.

2. The third basis for proposing rescission of a 510(k) SE decision is removal of a predicate device from the market for safety or effectiveness reasons or a judicial finding that the legally marketed predicate device is misbranded or adulterated. There are many characteristics of medical devices that collectively must be considered in rendering decisions regarding safety and effectiveness. Unless the specific reason for challenging the safety and effectiveness of the predicate implicates the device(s) that have cited the predicate, there is no reason to conclude the subsequent devices to be equally suspect. For instance a porous coated orthopedic implant having a porous coating different from a predicate, should not be considered suspect if the predicate's safety and effectiveness becomes questionable because of failure of that device's specific porous coating.

3. The fourth basis for proposing rescission of a 510(k) SE decision is a finding that the premarket notification contained or was accompanied by an untrue statement of material fact. There are already remedies to deal with material misstatements of fact in premarket notification submissions and the penalties for making such submissions are clearly available to redress this action by an individual or the company that they represent. Rescission does not appear to be necessary in this situation, although this is the one basis that would appear to be supportable on its face.

4. The fifth basis for proposing rescission of a 510(k) SE decision is the inclusion of clinical data that was gathered in a manner that failed to comply with the applicable requirements of 21 CFR Part 50 or Part 56 to protect the rights and safety of human subjects. The FDA has ample tools to enforce the requirements of Parts 50 and 56 in protecting the rights and safety of human subjects. This additional tool does not appear to be necessary to accomplish human subject protection. In addition, the test for applicability of clinical data in support of a 510(k) submission should be whether it adequately addresses the questions of safety and efficacy of the medical device being tested, not whether how it was conducted meets all the ancillary, yet essential protection requirements. The protection of human subjects certainly needs to be a

focus of attention for the Agency, but it is also true that clinical trials are often lengthy and the current interpretations of what constitutes adequate human subject safeguarding is in a state of flux. Existing rules and safeguards appear to be sufficient to the task without the remedy of rescission.

5. The sixth basis for proposing rescission of a 510(k) SE decision is the inclusion of clinical data submitted by a clinical investigator who has been disqualified under 21 CFR 812.119. The only appropriate basis for questioning the legitimacy of clinical data submitted by a disqualified clinical investigator should be evidence that the reasons for disqualification took place during the conduct of the trial in question and that they compromised the study conclusions regarding safety or effectiveness of the device. As with the fifth basis noted above, the FDA already has ample means to remedy noncompliant clinical investigators without the addition of a rescission remedy.

Because of the foregoing comments, Zimmer, Inc. strongly opposes the promulgation of this proposed rule as a final rule. There seems to be too little basis for its need; the FDA already has tools at its disposal to deal with the issues raised by the proposed rule as reasons for rescission. In addition, the FDA has not accurately assessed its economic impact on small entities, which can be great. The rule would also provide the Agency with new reclassification authority for reclassification of classes I and II into class III in apparent conflict with the intent of FDCA Section 513. (i)(C).

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