

June 4, 2002

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Docket No. 02D-0039
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Systems
Food and Drug Administration
5630 Fishers Lane
Room 1061
HFA-305
Rockville, Maryland 28052

To Whom It May Concern:

In response to the draft guidance document recently released by the Infection Control Branch "Premarket Notification (510(k)) Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA" we respectfully submit the following comments:

The CFR code cited in the guidance is inconsistent with the type of products described in the "Scope" and "Definitions" section of the document.

CFR 888.6850 is only applicable to sterilization containers that maintain sterility. Containers (cassettes, trays) with holes or perforations to allow steam penetration are not intended to "maintain sterility". In other words, the very nature of their intended use precludes them from classification as a class II devices according to CFR 888.6850.

Such devices fall into the LRP product code category as "surgical trays" (CFR 878.4800) and are therefore exempt from premarket notification requirements.

Adoption of the draft guidance as rendered would effectively reclassify instrument cassettes and bypass the reclassification procedures set forth by the Agency.

Furthermore, we recommend that such containers retain the FDA class I designation as these products meet all the criteria defined by the Agency for general controls.

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Class I devices are not intended to:

1. Be used in supporting or sustaining life,

Instrument cassettes or trays are accessories to reusable surgical instrument systems. They are not intended to come in contact with the patient and do not support or sustain life.

2. be of importance in preventing impairment to human life and

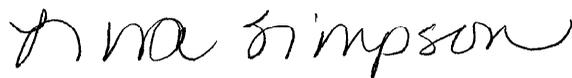
The cassettes or trays are not intended to prevent injury or harm to the patient but merely to house class I reusable instrumentation during transport, storage and steam sterilization.

3. may not present a potential unreasonable risk of illness or injury

Instrument cassettes or trays do not present an unreasonable risk of illness or injury. These containers do not pose additional risks of illness or injury above those already presented by the reusable surgical instruments they are designed to contain. In other words, whereas the contents of the instrument cassettes are class I devices so should the containers themselves be designated. Both products are supplied non-sterile and must be reprocessed by the health care facility. The overall inherent risks associated with cassettes or trays are less than those of reusable surgical instruments because these products are not intended for patient contact.

We appreciate the opportunity to comment on this material and work with the Agency on clarifying these important issues.

Sincerely,



Lisa Simpson
Sr. Regulatory Representative
Exactech, Inc.

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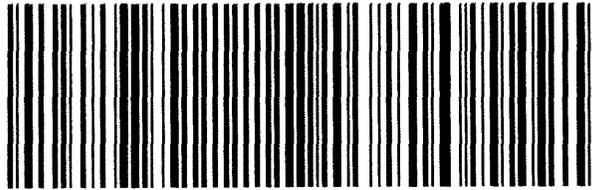
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