

HAEMONETICS®

HAEMONETICS CORPORATION
400 Wood Road
Braintree, Massachusetts 02184-9144
Telephone (781) 848-7100

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November 8, 2006

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

Re: Docket No. 2006N-0292

Dear Sir:

Haemonetics Corporation is pleased to submit the following comments on the recent FDA request for comments on Unique Device Identification (UDI).

We believe that FDA's implicit general assumption that medical devices today lack adequate means of identification is false. To our knowledge, virtually all medical device manufacturers use a method to identify their devices by means of a catalog number and a lot number or other manufacturing control number for disposable products, or a serial number in the case of durable equipment. This combination has served the industry well, as evidenced by the ability of the industry to monitor the performance of its products and its ability to conduct effective recalls.

We disagree with the FDA's assumption that the use of UDI will decrease medical errors. To our knowledge, there is no hard data in terms of how many errors now occur and how many could be eliminated because of UDI. The examples that FDA gives to improve safety, i.e. sterile vs. non sterile implants, would still be dependent on a operator to perform a verification check correctly whether reading labels or using a UDI system; thus the imposition of a UDI system is of questionable value.

We disagree as well with FDA's assumption that UDI will improve medical device adverse event reporting. The vast majority of medical devices in use today are single use disposables. Any device identification is typically contained on the packaging of the device, not on the device itself. In many cases, the user cannot identify the specific lot number or other means of identification when an event occurs because the packaging material is already thrown away. If we assume that any UDI system will remain on the device packaging materials, this problem still exists.

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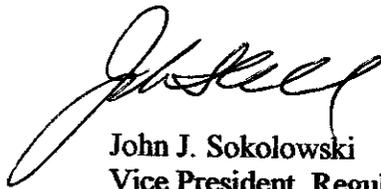
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In our opinion, this request for comments is attempting to address a non-problem. Any program requiring unique identifying information on every medical device would certainly add costs to these devices without a significant benefit to the public health. To the extent that the device industry in general already has systems for tracking individual products, in that most device companies use a catalog number and lot number scheme to identify their devices, the proposal would be duplicative.

Very truly yours,



John J. Sokolowski
Vice President, Regulatory Affairs