

Rebecca A. Stolarick
Director, Regulatory Affairs

B. Braun Medical Inc.
901 Marcon Blvd
Allentown, PA 18109

Telephone: 610-596-2536
Fax: 610-266-4962

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

Re: Docket No. 2006N-0292 Unique Device Identification; Request for Comments

Dear Sir/Madam:

B. Braun Medical Inc. welcomes the opportunity to provide the Agency with comments regarding Unique Device Identification. In particular, B. Braun Medical Inc. appreciates the Agency's consideration of the following comments.

B. Braun Medical Inc. is a large manufacturer of medical devices distributed in the United States. The majority of the devices manufactured by B. Braun are class II 510(k) cleared disposable and electronic devices used in the following clinical applications: IV therapy, pain control, vascular access, regional anesthesia, interventional, pharmacy admixture and dialysis. Due to the number of finished devices manufactured by B. Braun, B. Braun would incur additional costs to implement a Unique Device Identification system. The additional costs pose great concern to B. Braun.

B. Braun does not believe that implementation of a uniform, standardized, unique identification system is necessary for all medical devices. B. Braun currently has a system to identify B. Braun devices. This system incorporates the use of a bar code on the device labeling. Unless restricted by size, B. Braun places a bar code on all packaging levels for B. Braun devices. B. Braun utilizes the HIBCC and SSC 14 bar codes. The bar code contains the item number for the device. The device item number and lot number are also placed on the product label for identification and traceability. Additionally, each B. Braun electronic device contains a unique serial number. The bar code, item number, lot number and serial number on B. Braun devices provide an acceptable means for identifying B. Braun devices. If the customer uses this information, then these items also provide a means for customers to identify B. Braun devices.

Although the Agency believes that there is potential for Unique Device Identification to reduce medical errors, facilitate device recalls and improve adverse event reporting; there does not appear to be any data to support this. Additionally, there does not appear to be a problem with the current identification systems used by device manufacturers. If the Agency publishes a rule requiring medical device manufacturers to implement Unique Device Identification, device manufacturers will incur additional costs. Additionally, if device user facilities do not implement systems to utilize Unique Device Identification, then there would not be an opportunity to determine or take advantage of any true benefits of Unique Device Identification.

Implementation of a Unique Device Identification system would require substantial changes in B. Braun processes including label changes; bar code changes; and installation, validation and qualification of additional manufacturing equipment. These types of changes may impact normal production until all of the necessary changes are implemented. This could have negative impacts on product availability in the market place. All of the changes required to implement a Unique Device Identification system could also lead to increased product costs.

B. Braun believes that the costs to industry to implement Unique Device Identification far outweigh the benefits. B. Braun believes that there are many issues that need to be clarified by the Agency before publication of such a requirement. Some of these issues include the number and complexity of medical devices distributed in the US, global application of Unique Device Identification, use of Unique Device Identification from manufacturer to end user, and the type of devices that should be subject to Unique Device Identification. Due to the number of devices distributed in the US and the varying levels of risks associated with these devices, B. Braun believes that exemption from Unique Device Identification should be considered by the Agency for low risk and moderate risk devices.

B. Braun, respectfully requests that the Agency carefully consider the comments presented above. B. Braun Medical Inc. appreciates this opportunity to comment on Unique Device Identification and looks forward to continuing communication with the Agency to determine the best way to proceed.

Sincerely,

Rebecca A. Stolarick
Director, Regulatory Affairs