

November 3, 2006

Division of Dockets Management (HFA-305)
Food and Drugs Administration
5630, Fisher's Lane, Room 1061
Rockville, MD 20852

Subject: Comments on Unique Device Identification ref. Request for Comments (Docket No.2006N-0292)

Thank you for your "Request for Comments" on the above subject.

The requirement for a Unique Product Identification system for medical devices entails many considerations. We are listing some of these below and request you to consider them as you continue with the identification, planning and implementation process.

1. Identification system on devices will make traceability and patient error less likely and thereby contribute to patient safety.
2. Requirement of making an identification system mandatory should be sensitive to the "intended use" of the device - whether the device is life supporting etc., whether it is active/inactive, reusable or one time use. It might be advisable to draft a Guidance document containing an exhaustive list of devices and their identification requirements in a tabular form. As new devices are added, this list may be updated.
3. RFID could be an option in all cases, but not the only option in any case. While the technology is futuristic, it is not both human and machine readable. Considering that the device market caters to needs globally and to all levels of users, the identification system chosen should be both human and machine readable.
4. It would be advisable to use the identification system for only essential information and leave it to the discretion of the manufacturers if they want to give out any additional information via the same system. The size of medical devices is reducing constantly and space on medical devices is a major constraint. Due to International business and regulatory reasons, manufacturers will still have to include symbols and worded information on the device.
5. An identification system should be sensitive to existing mandatory medical device identification systems in other parts of the world e.g. Japan. This implies learning

from their experience, and reducing the burden on medical device manufacturers such that they do not have to maintain more than one system of identification for the same device and within the same organization. This will reduce price burden to the consumer.

6. The chosen system should be in line with a global system, which may be acceptable to all/most countries. Just like the Quality Systems, where we had the QSR, then the ISO standards, and now each country is coming out with their own quality system regulations, which are variations of the ISO standard. It will be a labeling tracking nightmare for manufacturers if each country's regulatory body comes out with their own identification system or variations of the same.
7. At all stages of planning and implementation, it should be considered if the current system is effective for each device, or will there be any "value addition" by inducting the identification system for that device. Induction of this system in unnecessary situations has a potential of increasing costs to manufacturers and indirectly to Insurance, Hospitals and Consumers – specifically at a time when rising health insurance costs are a major concern.
8. A long period should be given to manufacturers for clarifications, system validation and compliance, as mistakes in implementation would prove costly in terms of human health.

Thank you,

Regards,

Vikram Verma
Manager, RA/QA
Aspect Medical Systems, Inc.
141 Needham Street
Newton, MA 02464
Ph: 617-559-7000
Fax: 617-559-7400