MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today for Better Health Care Tomorrow™

1333 H Street, NW
Suite 400
Washington, DC 20005
P: (202) 354-7171
F: (202) 354-7176
www.medicaldevices.org

November 7, 2012

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

Re: Docket No. FDA-2011-N-0090, Proposed Rule
RIN N. 0910-AG31
Unique Device Identification System

Dear Sir or Madam:

The Medical Device Manufacturers Association ("MDMA") appreciates the opportunity to comment on the Proposed Rule, Unique Device Identification System, published in the Federal Register on July 10, 2012. MDMA is a national organization representing hundreds of innovative, entrepreneurial medical technology companies. MDMA's mission is to ensure that patients have timely access to the latest advancements in medical technology, many of which are developed by smaller, research-driven medical device companies.

MDMA supports FDA's efforts to enhance its ability to track medical devices for the purpose of ensuring patient safety. Properly executing a reasonable unique device identification ("UDI") system on appropriate products has the ability to assist FDA with its goal of ensuring that products are safe and effective. However, FDA must implement UDI in the most effective and cost-efficient manner possible. This transition will require the medical technology industry to spend significant resources to comply. With smaller companies facing a looming medical device tax, increased user fees and a reduction in venture capital investment, allowing as much flexibility and time to comply is critical.

Before highlighting specific areas of interest, MDMA would like to reaffirm comments submitted to FDA as early as 2006 which stated that FDA's UDI initiative must focus solely on issues within FDA's authority and should not involve areas outside FDA's jurisdiction. Specifically, MDMA is extremely concerned that certain hospital group purchasing organizations (GPOs) who seek to exclude competitive products from the marketplace because of their own financial interest will use UDI in a manner inconsistent with the public's best interest. The GPO industry has been the subject of multiple congressional hearings, federal and state investigations and various media reports documenting these exclusionary practices. Therefore, FDA must contain control of all data from the UDI initiative. Furthermore, this information should only be used for safety and efficacy issues and never for contract management purposes.

Priority Issues to be addressed in the Final Rule (Most are expanded upon in the comments submitted by Boston Scientific and the 510(k) Coalition)

1) The proposed date format is inconsistent with internationally recognized standards.

2) If FDA seeks to standardize the date format, it should make it applicable to all products it regulates.

3) Products manufactured prior to the rule's effective date should be expressly exempt from the requirements.

4) Requiring a new UDI for any change to the product or label would be overly burdensome to manage and extremely costly.

5) Devices already subject to tracking should be exempt from direct marking requirements.

6) The exemption process must be timely to allow adequate comment from interested parties prior to the effective date of the rule.

7) Reprocessors of single use medical devices subject to direct marking must ensure the markings of the original manufacturer are no longer present so the product can be traced back to the reprocessor.

8) MDMA believes FDA has underestimated the costs of the healthcare system from implementing UDI. As UDI is implemented, ongoing economic analysis must be conducted and appropriate steps taken to address unanticipated costs that arise.

9) To ease the economic burden to comply in these economically challenging times, FDA should allow two years after the final rule before requiring Class III product information to be included in the FDA database. All other deadlines should be extended accordingly by one year.

10) FDA should remove Latex and Sterilization attributes because it is beyond the scope of UDI. Furthermore, any attempts to expand attributes in the future must require appropriate public notice outlining FDA's justification to expand the attributes and allow for public comment.

11) Existing NDC and UPC codes on products should be acceptable for UDI labeling.

12) FDA should not conduct any investigations based solely on UDI information. If issues arise, the manufacturer should be notified to work collaboratively with FDA to explore the issue. This process should not be made public unless it is determined there is a significant patient safety issue by FDA and the manufacturer.

13) Given the stated intent of UDI to better enhance FDA's ability to ensure medical devices are safe and effective, FDA must maintain the database itself and not outsource the function to a 3rd party. Furthermore, FDA must not mandate that a company be required to contract with 3rd party non-government companies or agencies, especially those that charge fees for participation.

14) With the scope and complexity of this initiative, FDA should consider issuing a revised proposed rule before making the rule final.

15) Given the scope, effort and resources to comply, FDA should exercise enforcement discretion for two years to assist with this major transition.

In closing, MDMA appreciates this opportunity to comment on this important issue and looks forward to continuing to work with FDA to develop a reasonable, effective and appropriate unique device identification system.

Respectfully Submitted,

Mark B. Leahey
President & CEO
Medical Device Manufacturers Association