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

Re: Comments Concerning a Unique Device Identification System  
(Docket No. 2006N-0292)

Dear Sir or Madam:

On behalf of Welch Allyn, Inc. (Welch Allyn), the undersigned submits these comments in response to the Food and Drug Administration's (FDA) request for comments regarding a unique device identification (UDI) system.

Welch Allyn was founded in 1915 and is today a leading manufacturer of innovative medical diagnostic and therapeutic devices, cardiac defibrillators, patient monitoring systems, and miniature precision lamps. Welch Allyn focuses its efforts entirely on helping frontline practitioners in acute care and primary care by providing the tools required in family practice (including pediatrics, and OB/GYN), emergency medicine, internal medicine, and inpatient care medical disciplines. Headquartered in Skaneateles Falls, New York, USA, Welch Allyn employs more than 2,300 people and has numerous manufacturing, sales, and distribution facilities located throughout the world.

Welch Allyn supports the implementation of a reasonable UDI system for the purposes of facilitating the reporting of adverse events, the location of recalled products, and for conveying information to promote the safe and effective use of medical devices. The comments provided below represent our thinking on specific elements that should be considered by FDA in formulating such a system.

1. A UDI system must be international.

In light of today's market realities, a successful UDI system must be international in scope. When FDA promulgated the bar code label requirements for human drug products and biological products, the agency did not have to give a great deal of consideration to international trade. However, with regard to medical devices, international trade is a more pressing issue. There is generally a greater variety and amount of international trade in medical devices compared to drug

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and biological products. This is due to the varied nature of medical devices and lower regulatory barriers to market faced by manufacturers of many types of high, volume low-risk devices. A UDI system must, therefore, accommodate international trade. On the other hand, a UDI system will not be successful if other nations, agencies, or jurisdictions were to implement a different UDI system. For this reason, Welch Allyn believes that FDA must invite and encourage international participation and support for this UDI initiative toward a uniform system. Although we applaud FDA for taking up this issue, we believe that it is more appropriate for an international standards organization or an international medical device industry organization to administer any UDI system in order to ensure international harmonization and the ultimate success of the system.

2. A UDI system should be based upon a single technology.

Welch Allyn believes that the UDI system should be based upon a single technology (e.g., linear bar code, two-dimensional bar code, or radio frequency identification (RFID)). Bar code and RFID systems rely upon different hardware to "read" the encoded identification data. In the absence of an affordable hardware solution that will "read" both technologies, implementation of a UDI system using more than one of these identification technologies will be unduly burdensome since it will require users to invest in multiple "readers." The added expense of purchasing multiple "readers" will erase many of the efficiencies that may have been otherwise achieved through the implementation of a UDI system. Therefore, the UDI system should be based upon a single technology.

From Welch Allyn's perspective, there are several advantages to the adoption of a two-dimensional bar code system. First, two-dimensional bar code systems are capable of storing more data than can be incorporated into a linear bar code, and should be capable of encoding on a typical-size label device type classification, identifying serial or lot number, manufacturer, expiration date (where applicable), and perhaps a pointer to a database containing additional information. In addition, two-dimensional bar code system readers can be made capable of "reading" the traditional linear bar code technologies that are presently required in drug labeling. Thus, a UDI system based upon a two-dimensional bar code system can reduce the compliance burden placed upon health care facilities in that one "reader" system can be used for drugs and devices. Finally, two-dimensional bar code labeling could be incorporated into product labeling using processes that minimize the significant investments in new equipment that will be required for any UDI solution. A two-dimensional bar code system provides a UDI solution that is capable of encoding more data at a lower cost in a manner that is compatible with existing FDA bar coding requirements, and it appears that adopting a two-dimensional bar code system would be the most efficient and economic UDI solution.

On the other hand, we foresee certain disadvantages associated with implementing an RFID-based UDI system. The foremost disadvantage is the comparative cost of establishing an RFID-based system. In addition to the other costs associated with establishing a UDI system based upon a printed code, an RFID-based UDI system will also necessitate development of new labeling processes, a significant investment in new equipment, and the purchase of RFID transmitters. The additional costs associated with implementing an RFID-based system must either be absorbed by the manufacturer or passed on to the consumer. These expenses can add to the cost of health care and, at the margin, reduce its availability to the detriment of the public health.

3. For devices containing software, UDI coding should not include software revision data.

For devices that contain software that may be revised in the field, the UDI coding should not include software revision data. In many cases, software revisions are based upon operator preferences and feedback or are intended to fix "bugs" that do not significantly affect device safety or efficacy, such as menu shortcuts or improvements in graphics. As the device evolves, these revisions can be numerous and a UDI system that includes software revision data would necessitate mass relabelings of distributed devices. Such relabeling would be very difficult to implement and could require a recall-like procedure simply to maintain the relevance and integrity of the UDI system. Moreover, a UDI system that requires a manufacturer to track which of these changes have been applied to a particular device and the associated labeling revisions would require the establishment and maintenance of a tracking and labeling system that is beyond the financial and technical means of many device manufacturers. If implemented, such a requirement would drive up the costs associated with providing users with minor revisions to enhance device safety and efficacy and will discourage the implementation of changes that would otherwise enhance patient safety and the public health. Therefore, Welch Allyn does not believe UDI coding should include software revision data.

4. A UDI system should be mandatory and apply to all medical devices, but not all devices units should be physically marked with a UDI code.

To achieve the stated goals for the UDI system, it is Welch Allyn's opinion that the system should be mandatory for all device manufacturers and should apply to all medical devices. However, Welch Allyn does not believe that manufacturers should be required to put UDI labels on individual devices or accessories that are sold in packages containing multiple items. Disposable or single patient use products typically are sold in multiple item packages, for example thermometer probe covers, electrodes, blood pressure cuffs, vaginal specula, and spirometer flow tubes. In many instances, UDI labeling of individual accessories / devices would be unfeasible (e.g., size and materials limitations) or would add costs that make it economically unfeasible to continue producing the subject product. This situation potentially could reduce the availability of and access to commonly used devices to the detriment of the public health. Moreover, these types of devices are generally very simple items that are less likely to be associated with patient death or serious injury, or to be the subject of a device recall. Therefore, there is less need to individually mark these devices to facilitate medical device reports or product recalls.

Welch Allyn submits that where it is impractical or not feasible to mark devices or accessories with a UDI code, the UDI requirement should apply to packaging of the product and not to the device itself. Furthermore, the manufacturer should be permitted to designate the "minimum sales unit" of these items (e.g., the smallest size of packaging offered by the manufacturer) and the UDI labeling requirement should apply only to the minimum sales unit.

5. The UDI database should incorporate safe and effective use information.

Welch Allyn supports the secondary use of the UDI as a means to convey information to promote safe and effective use of devices. It is Welch Allyn's position that a supporting UDI database should contain information such as clinical attributes of the device, warnings, precautions, contraindications, and other information that would be useful to a healthcare provider, even though such information would serve no device tracking function.

6. A UDI system should be implemented over time and in phases.

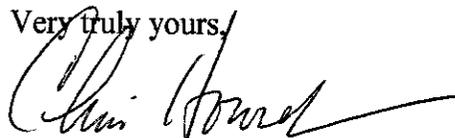
Even under the best case scenario, Welch Allyn expects device manufacturers' costs to implement a UDI system to be significant. So that these costs will not overwhelm the business operations of device manufacturers (especially smaller manufacturers), Welch Allyn suggests that it is appropriate to build in enough time between adoption and implementation of a UDI system to permit manufacturers to spread these costs out over time. Welch Allyn suggests that the best means to accomplish this goal is to implement the UDI system in phases by staggering the UDI compliance dates for different classes of devices, beginning with Class III and ending with Class I over a period of 3 - 5 years.

Conclusion

Welch Allyn supports the implementation of a reasonable UDI system for the purposes of facilitating the reporting of adverse events, the location of recalled products, and for conveying information to promote the safe and effective use of medical devices. However, Welch Allyn believes that any implemented UDI system should be international, be based upon a single technology, exclude software revision information, and incorporate safe and effective use information. Moreover, Welch Allyn believes that, while the system should be mandatory for all devices, the system should permit UDI labeling of manufacturer defined minimum sales units of accessories or disposables that cannot feasibly be marked individually. Finally, we urge the agency to implement the UDI program over time to reduce the economic impact it will have on medical device manufacturers.

We hope that you find these comments useful and welcome the opportunity to further comment on the agency's development and implementation of a UDI system.

Very truly yours,



Chris Horacek  
Vice President, Associate General Counsel  
Welch Allyn, Inc.