

COOK®

Cook Group Incorporated
750 Daniels Way, P.O. Box 1608
Bloomington, IN 47402-1608 U.S.A.

Phone: 812 331-1025
Fax: 812 355-6777
www.cookgroup.com

November 9, 2006

Mr. Jay Crowley and Mr. David Racine
Division of Dockets Management (HFA -- 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 2006N-0292

Dear Mssrrs. Crowley and Racine:

I am submitting these comments in response to the Food and Drug Administration's request for comments regarding unique device identification on behalf of the Cook Group Inc. Located in Bloomington, Indiana, Cook is a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, wound care, emergency medicine, and surgery. Cook pioneered the development of products used in the Seldinger technique of angiography, and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. Cook sells over 15,000 products which can be purchased in over 60,000 applications.

In opening, we would like to commend the FDA for addressing the issue of unique device identification (UDI). We believe that now is the time to develop a global system for UDI. We are living in the age of information technology, and UDI can enable us to take advantage of such technology to provide significant efficiencies at all levels of the health care supply chain as well as advancing patient safety and our understanding of how various medical technologies perform.

Cook is very grateful for the opportunity to submit these comments as well as for the opportunity for me to present our views at the Public Meeting regarding UDI held on October 25, 2006. I am attaching a copy of the Power Point Slides I presented at that meeting to these comments as they address some of the practical issues and costs a company faces in developing a UDI system.

2006N-0292

C9

Mssrs. Crowley and Racine
November 9, 2006
Page Two

I would like to emphasize that addressing UDI at this time is critical. Currently, most manufacturers put some type of code on their products or their packages. The problem is that there is no uniformity. Hospitals and other user facilities, faced with scores and scores of codes, have no practical way to systematically interpret the information presented in the codes and to use that information beneficially. Indeed, some hospitals develop their own bar codes that they paste on top of the bar codes provided by the manufacturer. Unless something is done, this will only get worse. Purchasers that are developing their own UDI systems will demand that manufacturers provide labeling consistent with the purchasers' own unique systems. Manufacturers will then have to develop multiple coding systems for their products. The inefficiencies that this will create will add significantly to the cost of medical technology with very little benefit to any of the stakeholders, most especially patients.

It makes much more sense to move now and develop a uniform system. That way every manufacturer can provide important coded information to purchasers, and purchasers can easily obtain equipment to read the codes and software to organize and store the information. The efficiencies this will create will produce savings for health care and for patients who in one way or another bear the costs of health care. Further, we believe a uniform system will promote the public health. In cases of product recall, there is no question that it will be easier for manufacturers to quickly identify exactly which products are problematic and which hospitals or other user facilities have purchased them. Indeed, manufacturers will have the ability to provide all this information to FDA as well as to the purchasers in a timely fashion. Equally important users of those products will be able to identify exactly which products must be removed from their shelves and returned as well as identify patients who have been affected by them.

In addition, if we move to a uniform UDI system and smartly develop systems for electronic medical records, we will be able to learn much more about the safety and effectiveness of medical technologies and therapies. Codes identifying devices used for patients could be read into the electronic records. Problems with those devices could then be identified more accurately and more promptly, and the effective use of devices could be confirmed more easily. Indeed, comparison of various technologies and device types will become much more feasible. In the end, this will benefit patients, which is the ultimate goal of all the stakeholders, including regulators and payers.

The first step that must be taken is for FDA to develop a standard which defines exactly what information should be furnished for each device. Once this is done, there are several systems and technologies that can be employed.

In terms of technology, the choices at this time are between barcoding and RFID. We recommend that FDA embrace barcoding for the time being. There are problems with RFID in terms of devices that

Mssrs. Crowley and Racine
November 9, 2006
Page Three

include incompatibility with gamma sterilization, potential interference with metals in devices, and potential frequency interference with other hospital equipment. Also, and importantly, the cost of RFID is relatively high compared to barcoding. We should seek to avoid adding unnecessary costs to the system in this country and, indeed, around the world. It will be difficult for institutions in many countries to afford the equipment and software needed to effectively utilize barcoding, and this problem would be exacerbated if we moved too quickly to RFID. Further, unlike barcoding that can be read even without special equipment, those institutions that are not properly equipped have no way of gaining information about products identified with RFID.

There are several barcoding systems available in the market place. At Cook, we chose EAN-128 (GS1) because we believed it provides the most flexibility in providing information, but other existing systems or new systems could be used to provide the essential data. Equipment and systems to read multiple systems and organize and store pertinent information are readily obtainable once the essential elements of information are defined.

In determining what information should be required in the UDI system, we recommend that FDA emphasize simplicity so that UDI can be easily and, more importantly, promptly adopted. We think it is essential that the requirements be consistent with what is required currently in other countries and that FDA take the lead in promoting universal acceptance of the standard.

As we see it, the essential elements of information are the following:

- The manufacturer
- The product number
- The lot or batch number
- The expiration date

There are unquestionably other items that some might find useful to include, but each item adds to the costs and will cause delay in implementation. Those items listed above provide the essentials that will enable us to reap the benefits of information technology discussed above.

The agency suggests in its request for comments that the UDI could interface with a computer database that could access an additional reference data set with information related to safe use of a device, accessories, etc. etc. etc. We recommend that the development of such a universal database, or Public Data Utility (PDU), be postponed indefinitely. It would be extremely expensive to develop and maintain and could inordinately delay or derail the effort to establish a UDI system. At this time, we should

Mssrs. Crowley and Racine
November 9, 2006
Page Three

concentrate on stimulating the development of systems which will enable buyers and sellers to perform more effectively and better serve patients in the near term future. We believe the proposed database is extraneous to that mission.

There are a number of questions that may be addressed on how devices should be coded. For example, for some products it will be practical to place a barcode on the product itself. For others it will be feasible only on the package. We are confident that these issues can be resolved with input from stakeholders without much difficulty.

Cook appreciates the opportunity to comment on the proposal for a unique device identification system, and we look forward to working with FDA on this very important subject.

Respectfully,

A handwritten signature in cursive script that reads "Chuck Franz".

Chuck Franz
Vice President and CIO
Cook Group Inc.

Design & Implementation of Unique Identifiers

Chuck Franz
Vice President & CIO
Cook Group Inc.

COOK

Barcode vs. RFID

- Barcode
 - EAN Standard
 - Easy Implementation
 - Accepted Globally
 - Required in Japan
- RFID
 - Not compatible with Gamma sterilization
 - Potential interference with metals in devices
 - Potential frequency interference with other hospital equipment
 - Potential RFID hacking/counterfitting
 - Costly

Cook EAN-128 Implementation

- Total Unique Cook Products (Part Numbers)
 - 2001 = 27,000 part numbers
 - 2003 = 17,000 part numbers
- Project began in Europe – 2001
 - Meet regulatory requirements in Japan
- Project Complete – April 2002
 - Internal
- Project Complete – January 2003
 - Global customers

COOK

EAN-128 Barcode (or GS1)

EAN-Number/Product: (01) 0 08 27002 00166 4
(01) Application Identifier for EAN-Number/Product
0 Pack Indicator
08 USA (00-09 = USA & Canada)
27002 Manufacturer
00166 Product
4 Check Digit (Calculated using string 0082700200166)

Exp Date: (17) 091019
(17) Application Identifier for Expiration Date
091019 Expiration Date (YYMMDD)

Variable Qty: (30) 5
30 Application Identifier for Variable Qty.
5 Variable Qty.

Batch Number: (10) E1231234
(10) Application Identifier for Batch Number
E1231234 Batch Number

COOK

Required Materials

- Cost of EAN Numbers \$750-\$50,000
- Printer \$4625
- Set-up 2 hours
- Validation 1 week

Implementation

- Market Notification 3 months
- Company Switchover
 - Local (8 locations) 1 month
 - Global 12-15 months
- Customer Switchover ???

Questions & Panel Discussion

REF
AX1-1-22-125
ZENITH™ RENU™ AORTOUNI-ILIAC AAA ENDOVASCULAR GRAFT
WITH THE H&L-8 ONE-SHOT™ INTRODUCER SYSTEM

A = 22mm B = 125mm C = 12mm D = 19.Df E = .035" F = 40cm

U.S. PATENT NUMBERS: 4,590,563; 5,456,713; 5,562,726
 OTHER PATENTS PENDING AND GRANTED

LOT LOT NO. SAMPLE
REF

GPN # **REF** G00000

USE BY 2006/10 **MANUFACTURED** 2004/10 **STERILE EO**

CE 0123

EC REP AX1-1-22-125
 WILLIAM COOK EUROPE A/S
 Sandet 6 DK - 4532
 Bjerzerstov DENMARK
 Phone: +45 56 86 86 86

(01)00827002000000(17)061026(10)SAMPLE

COOK Cook Incorporated * 750 Daniels Way * P.O. Box 499
 Bloomington IN 47402-0489 * www.cookgroup.com
 Phone (812) 339-2235 * U.S. Toll Free (800) 457-4500

AZ

COOK