November 8, 2006

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

RE: FDA Response to Docket No. 2006N-0292 – Unique Device Identification (UDI) for Medical Devices

Dear FDA:

The following information is being provided by TherMark Holdings, Inc. of Los Angeles, CA (incorporated in Delaware in 2006 as a "C" corporation) in response to your request for comments on Docket No. 2006N-0292. We have responded to certain of the twenty (20) questions in your Notice, those to which believe we are well qualified to respond. Our responses are provided in *red italicized text*.

The following background is being provided to the FDA to advise it that contrary to what some medical device manufacturers might indicate, that there is in fact a commercially viable means for marking virtually any device or part for only pennies per part.

Background

TherMark has been involved in laser marking/bonding and industrial product identification since 1997. This involvement includes a wide range of industries such as medical/surgical instrumentation, automotive components and assemblies, aerospace parts, and Department of Defense assets. We have several leading customers who use our patented technology to mark and identify medical devices.

Founded as TherMark Corporation by Paul Harrison in 1996, TherMark Holdings, Inc. has grown to be an expert in laser marking technology. TherMark's patented laser marking process quickly produces permanent, high-contrast, high-resolution marks, in an assortment of colors, on a variety of surfaces including metals, ceramics, glass, porcelain, plastics, marble, granite and stone.

In April 2006, the company received $1.7 million in Series A funding, led by Tech Coast Angels and Pasadena Angels, both of Southern California, to meet the growing worldwide demand for permanent laser marking, especially in the arena of Direct Parts Marking (DPM). The company's first acquisition came in July 2006, with the purchase of TherMark-related assets from Advanced Identification, Inc., also an expert in parts identification.

TherMark maintains its headquarters in the Greater Los Angeles area with sales and support offices in Pittsburgh and Nuremburg, Germany.

Since its inception, the company has diligently worked to improve its laser marking technology and products on an ongoing basis. TherMark has expanded its capabilities to serve a global audience across a broad spectrum of industries including awards and recognition; signage; medical and surgical instruments; automotive; home appliances and décor; manufacturing; and aviation and aerospace. TherMark is changing the face of decorative and industrial marking today just as Xerox revolutionized

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document copying 50 years ago. TherMark's process is the only method currently available that meets the full range of requirements for the highest quality in laser marking.

TherMark's technology encompasses a portfolio of U.S. and foreign patents as well as patent applications, which together represent a dramatic step forward in product decoration, marking and identification. Currently, this portfolio consists of 27 granted U.S. and foreign patents in addition to other patent applications pending in the United States and other major foreign markets.

The company holds major licensing and product development agreements with Ferro Corporation for the development and supply of pigments to mark and decorate all glass, ceramic, porcelain and metal surfaces as well as with Tesa AG of Hamburg, Germany, for tape and label products used in dry transfer marking and decorating of all basic surfaces.

TherMark is dedicated to developing the highest quality and most cost-effective laser marking technology and materials, enabling improved productivity and innovation for its customers. The company adheres to the highest standards of integrity and safety, continually pioneering methods to improve its products and support services.

Thermark™ Laser Marking Technology

The TherMark process utilizes marking materials, or "inks," available in various forms, which are applied to surfaces to be marked. The ink is then selectively fused – using patented laser marking technology - to the surface with a regular industrial marking laser. Finally, any excess ink is easily cleaned from the surface. The inks are scientifically formulated to make a permanent, chemical bond to surfaces, without compromising or damaging the material being marked.

TherMark marking materials are available as paintable liquids, aerosols or adhesive transfer tapes. The paintable liquid may be applied to surfaces with a brush, sponge or air sprayer. After fusing with the laser, any excess paintable liquid or aerosol spray can be cleaned from the surface by simply rinsing with water. Tapes are applied to surfaces using their own light adhesives. After fusing with the laser, the tape is lifted from the surface, carrying away any excess marking material. The used tape is then discarded.

Regardless of the application, the end result is a durable, high-contrast and high-resolution mark.

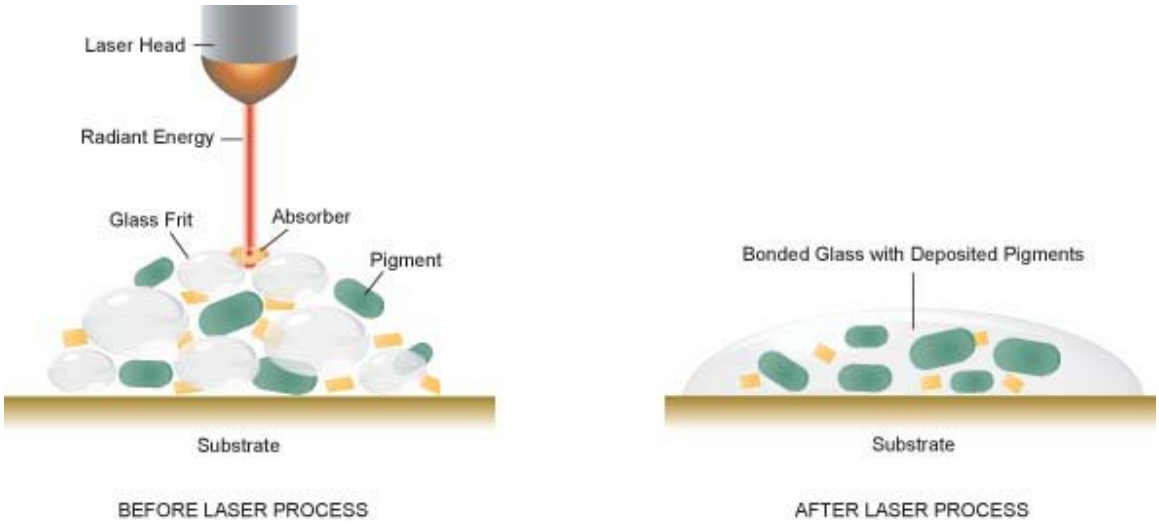
The revolutionary TherMark process uses precise lasers and marking materials scientifically formulated to permanently fuse to metals, ceramics, glass and other hard surfaces for high-contrast, high-resolution marks. TherMark's patented technology offers an unmatched combination of benefits that stems directly from the chemistry involved in its laser marking process.

TherMark's marking materials, or inks, consist of traditional ceramic glazing material, with the addition of a thermal absorber.

The ceramic glazing material is a mixture of glass frit – small particles of partially fused glass designed to melt at a much lower temperature than ordinary window glass – with pigments for coloring. The traditional use of such glazing material requires it to be applied to the surface of a ceramic object, and then baked in a very hot kiln for more than an hour. Once fired, the glass frit and pigments combine to form a thin layer of colored glass that is further fused onto the surface of the ceramic object.

The patented TherMark method uses a laser as the heat source to fuse the ceramic glaze instead of a kiln. All this happens in microseconds as opposed to hours, consuming far less "energy" and, consequently, without compromising or damaging the material being marked. It is the thermal absorber within the

TherMark marking materials that enhances and speeds the heat absorption from the laser beam, improving the transfer to the glaze.



The Advantages of TherMark™ Laser Marking Technology

The TherMark laser marking process has a unique combination of strengths that puts it ahead of all other methods for marking hard surfaces. Most notably, the TherMark process can quickly produce permanent, high-contrast, high-resolution marks, in an assortment of colors, on a variety of surfaces, without compromising or damaging the material being marked. There is not an alternative laser marking technology on the market today that can match these proven results.

The following table provides a more detailed and extensive comparison of the TherMark laser marking process against alternative marking technologies.

Comparison of TherMark Marking Process to Alternative Processes

Value 0 = Low 9 = High	Direct Laser Marking	Inkjet Printing	Screen / Pad Printing	TherMark Process
High Contrast	5	9	9	9
High Resolution	9	9	5	9
Marking Speed	9	9	3	9
Mark Permanence	9	3	3	9
Variable Data	9	9	0	9
Custom Colors	0	5	5	5

Digital Decoration	0	9	0	5
Abrasion Resistance	5	2	2	9
Chemical Resistance	5	5	5	9
Temperature Resistance	5	2	2	9
Variety of Materials	3	7	7	8
Cost Per Mark	9	9	6	9
Hardware Cost	2	6	8	2
Total Value	**70**	**85**	**52**	**101**

TherMark Responses to Certain FDA Questions

2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

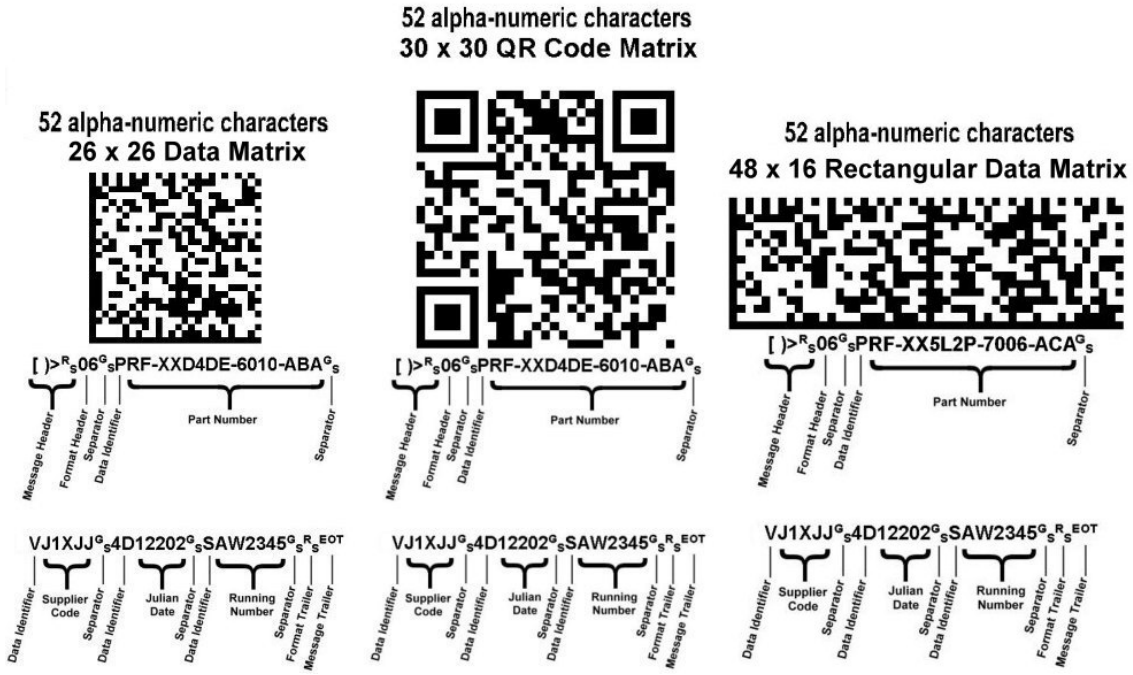
The FDA should take an active role in the standardization of mandatory Medical Device Identification Standards. Standardization should include recommended marking methods and data content requirements. The UID system implemented by the Department of Defense can be a guide. Such standardization can help ensure that required/approved devices are identified properly and provide satisfactory UDI code readability.

4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?

- *Symbology/information and data conveyance and capture – standardize on a symbology and the data that must be conveyed*
- *Different device types – define those devices that are critical to patient safety*
- *Different surfaces and difficulty in marking/labeling the myriad of surfaces- metal, plastic, ceramic, glass – the mark should be permanent to ensure patient safety*
- *Different marking methods- recommend methods that can mark/identify a variety of surfaces*
- *Cost – both capital investment and operating costs – the methods must be commercially viable (less than $0.10 per mark)*
- *End user (hospitals, patient care facilities) adoption and timeline – manufacturers, not users, required to uniquely identify their products/devices (serial numbers)*
- *Manufacturing adoption and implementation timeline – within 3 years of issuing regulations*

6. Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?

Yes, unique device identifiers should be considered for critical devices (e.g., surgical instrumentation) that affect patient safety. Ford Automotive originally used data identifiers (original layout below).



11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

Yes, you need to have human readable data whenever possible to document device information in case a code reader is not available. Permanent human readable information needs to be present just as much if not more so on RFID tags since RFID readers are even less common then bar code readers. RFID paper labels are having around 10% failure rate even before they are encoded. Very few RFID tags are designed to work on metal or survive medical instrument sterilization processes.

12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be compatible" with those used for the drug bar code rule? If yes, why?

We believe that the FDA should standardize on a specific symbology technology. There are over 250 different types of codes and symbols. In our opinion, the best symbology ever developed for direct parts marking is the InfoGlyph code (www.infoglyph.com) since it can convey hundreds of characters of information and be reliably read on curved and textured surfaces by simple $50 webcams. The only drawback is that this is not an open code and you have to pay a royalty for its use. Other options are what is most widely used for marking parts in industry, the Data Matrix code. Linear bar codes such as 3 of 9 and I 2 of 5 are not recommended as they can only convey limited data, do not allow for error correction, and are not reliable on curved and textured surfaces.

14. From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.

CO2 Lasers cost approximately $12,000 each. High-power YAG lasers cost approximately $55,000. Fully automated solutions which provide for high speed (1 mark per second) in-line manufacturing and indexing of marks can cost up to $250,000-$1,000,000 in capital investment. A computer-generated laser bonded mark applied using the Thermark™ Technology costs approximately 2-5 cents per mark, which includes the amortization costs of the capital investment with laser bonding.

16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?

We have seen that manufacturers of medical devices are more likely to implement these technologies than hospitals. Many hospitals comment that they do not have the funds to implement these kinds of programs. However, recently, we have been able to provide laser marking systems that cost $12,000 and about 20 hospitals are now marking their own instruments and tracking them.

19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes?

Software can be written to announce a warning when a device is scanned that needs to be returned for a recall or has passed its' expiration data. Hospitals do not currently posess bar code readers capable of reading the Data Matrix code. If the code is a small laser mark on metal the reading device are much more specific that they have to use. 99% of current Data Matrix code readers are not made to read direct marks.

How costly are these advancements?

Direct mark Data Matrix code readers cost from about $1,500 to $3,500. Verification devices that grade directly marked Data Matrix codes cost around $13,000. We only know of one unit in the world that is capable of reading both directly marked Data Matrix and RFID. This unit is currently around $5,000.

Sincerely,

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