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Exhibit 99.2

[SEAL] DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2004

James Santelli
Vice President, Finance and Chief Financial Office
Digital Angel Corporation
490 Villaome Avenue
South Saint Paul, Minnesota 55075-2443

Re: K033440
Evaluation of Automatic Class III Designation
VeriChip(TM) Health Information Microtransponder System
Regulation Number: 21 CFR 880.6300
Classification: Class II
Product Code: NRV

Dear Mr. Santelli:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the VeriChip(TM) Health Information Microtransponder System, a prescription device, as per 21 CFR 801.109, that includes the VeriChip(TM) Pocket Reader and the VeriChip(TM) with the insertion device. The VeriChip(TM) Pocket Reader is indicated for use as a portable instrument that non-invasively reads the ID number of an implantable microchip that is inserted into the arm of the patient. When activated, the VeriChip Pocket Reader displays a unique identification number that may be used to access the patient's identity and authorized health information from a secure database. The VeriChip(TM) is indicated for use as a miniature, implantable microchip that is inserted into the subcutaneous tissue of the patient. The VeriChip(TM) provides the patient a unique identification number that may be used to access a database containing the patient's identity and health information.

FDA has determined that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the VeriChip(TM) Health Information Microtransponder System, and substantially equivalent devices of this generic type into class II under the generic name, Implantable Radiofrequency Transponder System for Patient Identification and Health Information. This order also identifies the special control applicable to this device, entitled, "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information."

FDA identifies this generic type of device as:

21 CFR 880.6300 Implantable Radiofrequency Transponder System for Patient Identification and Health Information

Page 2 - Mr. Santelli

An implantable radiofrequency transponder system is intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code which is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On August 4, 2004, FDA filed your petition requesting classification of the VeriChip(TM) Health Information Microtransponder System into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on July 22, 2004, automatically classifying the VeriChip(TM) Health Information Microtransponder System in class III, because it was not within a type of device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the VeriChip(TM) Health Information Microtransponder System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Page 3 - Mr. Santelli

Based on the information submitted in the petition for the VeriChip(TM) Health Information Microtransponder System, FDA has determined that the VeriChip(TM) Health Information Microtransponder System can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

The potential risks to health associated with the device are: adverse tissue reaction; migration of implanted transponder; compromised information security; failure of implanted transponder; failure of inserter; failure of electronic scanner; electromagnetic interference; electrical hazards; magnetic resonance imaging incompatibility; and needle stick. The special controls document aids in mitigating the risks by identifying performance and safety testing, and appropriate labeling. Thus, in addition to the general controls of the act, an Implantable Radiofrequency Transponder System for Patient Identification and Health Information is subject to the following special control: Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of an Implantable Radiofrequency Transponder System for Patient Identification and Health Information and, therefore, the device type is exempt from the premarket notification requirements. Thus, persons who intend to market this device type need not submit to FDA a premarket notification submission containing information on an Implantable Radiofrequency Transponder System for Patient Identification and Health Information, unless they exceed the limitations on exemptions in 21 CFR 880.9 (e.g., different intended use or fundamental scientific technology).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation will be on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and will be available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order. If you have any questions concerning this classification order, please contact Gail Gantt, R.N. at (301) 594-1287.

Sincerely yours,

/s/ Donna-Bea Tillman
Donna-Bea Tillman, Ph.D
Director
Office of Device Evaluation

Center for Devices and
Radiological Health

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