Center for Devices and Radiological Heath

Office of Communication, Education and Radiation Programs  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Watson Megatech, Inc.

% Chad Watson

Dec 1, 2011

President and CEO

5800 Industrial Blvd

Suite 11

Omaha, NE 68135

Re: P091462

BioBanking

Filed: Jan 9, 2010

Amended: August 5, September 8 and 13, 2010; February 22, 2011; September 22, 2011; October 6, 2011 and November 1, 2011.

Procode: RLD

Dear Mr. Watson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration

(FDA) has completed its review of your premarket approval application (PMA) for the BioBanking Device.

BioBanking is intended to be for sub-dermal use as a radio frequency (RF) emitter in the prevention of identity theft and financial fraud. The device will interact with external scanners through radio frequency to identify the individual as well as financial account information. The device will also interact with external encoders for the purposes of addition or removal of financial account information. The device is solar powered and does not need internal batteries that would provide potential medical issues in the PMA review process.

The BioBanking insertion process can be administered by non-medical personnel trained in the implementation of the product. Financial institution personnel responsible for this administration will be trained and certified in application of the BioBanking device.

The sub-dermal BioBanking device is one element of the total transaction system. There is also a reader for the RF signals. Since the reader is a passive device it does not fall under provisions of the CDRH purview.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution

of the device in accordance with the conditions of approval described below. You may continue

commercial distribution of the device upon receipt of this letter.

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The sale and distribution of this device are governed by The Radiation Control provisions (originally enacted as the Radiation Control for Health and Safety Act of 1968) located in Sections 531 through 542 of the Act. They apply to any "electronic product" which is defined as: any manufactured or assembled product (or component, part, or accessory of such product) which, when in operation,

1. contains or acts as part of an electronic circuit and
2. emits (or in the absence of effective shielding or other controls would emit) electronic product radiation.

"Electronic product radiation" is defined as:

1. any ionizing or non-ionizing electromagnetic or particulate radiation, or
2. any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

The device is restricted under section 515(d)(l)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary' to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Continued approval of this PMA is contingent upon the submission of periodic reports, required

under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of

approval of the original PMA. Two copies of this report, identified as "Annual Report" (please use this title even if the specified interval is more frequent than one year) and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and

effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

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In addition to the Annual Report requirements, you must provide the following data in post approval study reports (PAS). Two copies, identified as "PMA Post-Approval Study Report" and

bearing the applicable PMA reference number, should be submitted to the address below.

1. You must conduct a post approval study that will evaluate whether BioBanking causes adverse skin reaction in the majority of consumers where it is implemented.

2. The study will be a multi-center, single arm, observational, prospective study to gather data

on whether the insertion procedures introduce pathogens into the consumer. The study must be completed on a statistically relevant set of consumers and the findings independently verified.

FDA would like to remind you that you are required to submit separate PAS Progress Reports

every six months during the first two years and annually thereafter. The reports should clearly be

identified as Post-Approval Study Report. Two copies for each study, identified as "PMA Post-

Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance

document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

([www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974htm#2](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974htm#2)).

Be advised that the failure to conduct any such study in compliance with the good clinical

laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a

complete protocol of your post-approval study. Your PMA supplement should be clearly labeled

as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please

reference the PMA number above to facilitate processing. If there are multiple protocols being

finalized after PMA approval, please submit each protocol as a separate PMA supplement. For

more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

([www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2)).

Before making any change affecting the safety or effectiveness of the device, you must submit a

PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39.

All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process"

(ww\v.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

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CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at:

www.fda.gov/RadiologicalDevices/Products/DeviceApprovalsandClearances/PMAApprovals/default.htm.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of

approval of a PMA. The introduction or delivery for introduction into interstate commerce of a

device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the" final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive.

U.S. Food and Drug Administration

Center for Devices and Radiological Health

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If you have any questions concerning this letter, please contact Atiq Chowdhury at 301-796-6391.

Sincerely yours,

Christy Foreman

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Food and Drug Administration