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## Translation of "Dr. Julio García- Response Letter" from "SPANISH" to "ENGLISH"

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David Abrameto, VP of Operations

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Dated: April 28, 2015





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MSP Ministry of Public Health

CONABIOS

National Council of
Bioethics in Healthcare

Santo Domingo, N.D. March 4, 2014

To: Dr. Julio Luis García, Biomolecular LLC

Dr. Oresteban Carabeo, Biomedical

Cc: Dr. Lorenzo W. Hidalgo Nuñez, Ministry of Public Health

Cc: Gustavo Montalvo, Ministry of the Presidency

From National Council of Bioethics in Healthcare (CONABIOS)

Distinguished Recipients,

We hereby wish to greet you, on the occasion of responding to your correspondence received on the 24<sup>th</sup> of February of 2014, and read by this Council at its regular session held on the 25<sup>th</sup> of February of 2014, wherein our approval is sought for the Implementation of the Dendron Soma Electromechanical System for Type II Diabetes Mellitus, to be applied in the Dominican Republic.

In this regard, the Council communicates: That under the provisions of Administrative Order No. 0000012, of the Ministry of Public Health and Social Assistance (SESPAS), dated October 10<sup>th</sup>, 2008, The National Council of Bioethics in Healthcare (CONABIOS), is the government agency responsible for regulating research involving humans in the Dominican Republic; Therefore, if a particular protocol does not correspond to a clinical investigation, it need not be authorized, known or approved by this Council. It is not the responsibility of this Council to authorize, approve or disapprove treatments and procedures that are not part of a protocol for biomedical research.

Without further ado, we send our sincere salutations,

[Signature] [Stamp: [Signature]

Aura Celeste Fernández R. CONABIOS Dr. Miguel A. Montalvo B. President National Council of Bioethics Executive Director

in Healthcare]

ACFR/MAMB/mcc

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