Certificate of Compliance with FDA Guidance

This certifies that Cell Wellbeing's S-Drive qualifies as a general wellness device as defined by the United States Food and Drug Administration Center for Devices and Radiological Health's compliance policy entitled 'General Wellness: Policy for Low Risk Devices' issued on July 29, 2016", FDA guidance 1300013 (UCM429674).

A general wellness device compliant with FDA guidance 1300013 (UCM429674) has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

The S-Drive has an intended use that relates to supporting, maintaining or encouraging a general state of health or a healthy activity. In general, claims in this category include weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, and sexual function. The various Optimize reports contain information pertaining to the state of general health through dietary, nutritional, and supplement programs, as well as making statements relating to support of the overall physiology of the body. Importantly, these statements do not make any reference to a particular disease or condition.

The S-Drive is neither invasive nor implanted, and does not involve a technology that may pose a risk to the safety of users or other persons if specific regulatory controls are not applied, such as, for example, risks from lasers or radiation exposure.

The following is the UL/ETL approved description of the S-Drive:

Product Description	
Product	Cell profiler
Brand name	CWB
Description	The CWBCE-1320 is a cell profiler used to observe the resonant frequencies of specimens. The equipment is powered from a single USB connection to an external computer which runs software that collates specimen information and the data provided by the cell profiler. The cell profiler generates a magnetic field that grows in the coil and grows in the field (low field). Different specimens affect differently the fields (growing and decaying), the resonant medium of microactivity is then assessed by a bio-information centre against relevant and data stored indicators, for example organic/biological and returned to the sender
Models	CWBCE-1320
Model Similarity	NA
Ratings	5Cdc, 30mA
Other Ratings	NA
Conditions of Acceptability	The products covered in this Report are incomplete in construction features or limited in performance capabilities and are intended for use and evaluation in other products. Consideration should be given to the following when the component is used in or with another product: 1. The equipment is only to be connected to an external computer with a USB port that conforms to USB standard 1.1, 2.0 or 3.0. The equipment is not suitable for use with higher than USB standard 3.0 unless further single fault conditions are performed on the equipment using the maximum declared supply current available from the future USB standard number. 2. The computer that the equipment is connected to via the USB connection must provide double/reinforced insulation to mains voltages.

Based on the above analysis, I affirmatively certify that Cell Wellbeing's S-Drive is compliant with FDA guidance 1300013 (UCM429674).

Authorized Regulatory Advisor

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