

To Whom It May Concern:

This letter confirms that the S-Drive produced by Cell Wellbeing, Ltd. qualifies as a general wellness product under 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 product that is 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 clearly meets the above requirements. The S-Drive has an intended use that relates to supporting, maintaining or encouraging a general state of health. The S-Drive detects epigenetic signals that influence gene expression, so that changes to diet, nutrition and lifestyle can be adopted to support optimal physiology and performance. 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. Importantly, the S-Drive is not intended to diagnose, treat, cure, or prevent disease, as expressly stated on the reports that are generated from the S-Drive.

Based on the above analysis, it is my expert opinion that the S-Drive is fully compliant with FDA guidance 1300013 (UCM429674).



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Authorized Regulatory Advisor

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