CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 031 **Date of Recognition:** 09/29/2023

SDO Name/Designation: ISO 10993-1 **Year of Publication:** 2018

Title: Biological evaluation of medical devices —Part 1: Evaluation and testing within a risk management process

Scope:
This document specifies:
— the general principles governing the biological evaluation of medical devices within a risk management process;
— the general categorization of medical devices based on the nature and duration of their contact with the body;
— the evaluation of existing relevant data from all sources;
— the identification of gaps in the available data set on the basis of a risk analysis;
— the identification of additional data sets necessary to analyse the biological safety of the medical device;
— the assessment of the biological safety of the medical device.
This document applies to evaluation of materials and medical devices that are expected to have direct or indirect contact with:
— the patient's body during intended use;
— the user's body, if the medical device is intended for protection (e.g., surgical gloves, masks and others).
This document is applicable to biological evaluation of all types of medical devices including active, non-active, implantable and non-implantable medical devices.
This document also gives guidelines for the assessment of biological hazards arising from:
— risks, such as changes to the medical device over time, as a part of the overall biological safety assessment;
— breakage of a medical device or medical device component which exposes body tissue to new or novel materials.
Other parts of ISO 10993 cover specific aspects of biological assessments and related tests. Device specific or product standards address mechanical testing.
This document excludes hazards related to bacteria, moulds, yeasts, viruses, transmissible spongiform encephalopathy (TSE) agents and other pathogens.

Extent of Recognition: Partial Recognition

Rational for Recognition: Portions of this standard are not consistent with CDRH/CBER guidance. Annex A, Table A.1 is not recognized.

Standards Development Organization: https://www.iso.org/

Please note that this standard may also be recognized under the Center for Devices and Radiological Health's (CDRH) Recognized Consensus Standards Database for Medical Device, found here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm