ICS 11.060.10
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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0127.19-2023

Biological evaluation of medical devices used in dentistry - Part 19: Subacute and subchronic systemic toxicity test: implantation route

口腔医疗器械生物学评价 第19部分：亚急性和亚慢性全身毒性试验：植入途径

Issued on: November 22, 2023 **Implemented on: December 1, 2024**

Issued by: National Medical Products Administration

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document is part 19 of YY/T 0127 Biological Evaluation of Oral Medical Devices. YY/T 0127 has been published for the following part.

---YY/T 0127.1 Biological test methods for oral materials-Hemolysis test;

---YY/T 0127.3 Biological evaluation of oral medical devices Part

3.Root canal application test;

---YY/T 0127.4 Biological evaluation of oral medical devices Part

4.Bone implantation test;

---YY/T 0127.5 Biological evaluation of oral medical devices Part

5.Inhalation toxicity test;

---YY/T 0127.6 Biological evaluation of oral materials Unit

2.Biological test methods for oral materials Dominant lethal test;

---YY/T 0127.7 Biological evaluation of oral medical devices. Part

7.Application tests on pulp and dentin;

---YY/T 0127.8 Biological evaluation of oral materials Unit

1 Scope

YY/T 0127.19 specifies how subacute and subchronic systemic toxicity is tested when a dental device material reaches the body by implantation rather than by ingestion or skin contact. It sets out the test methods for that route: the exposure period, the way the material is presented to the test system, and the observations and analyses that reveal whether repeated or prolonged contact produces effects away from the implant site. Dental materials sit in the mouth for years, and a filling, a cement or an implant surface releases substances the whole time, which is why the systemic question is asked separately from the local one. This is the part of the Chinese dental biocompatibility series a reviewer applies to that question, and the 2023 edition is the text in force.

This document describes the systemic toxicity test methods for subacute and subchronic implantation routes of medical devices for oral health. This document is applicable to subacute and subchronic systemic toxicity tests for evaluating oral medical devices for implantation routes.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 16886.2 Biological evaluation of medical devices Part

3 Terms and definitions

GB/T 16886 (all parts) and the following terms and definitions apply to this document.

3.1 dose; dosage The amount of test sample given per unit body weight or surface area (e.g., volume, mass). g, mg), or the surface area or mass of the test sample per unit surface area or body weight of the animal (cm2/m2, m2/m2, mg/kg, g/kg).

3.2 Degradable biodegradable The material may be induced to break down by the biological environment or the breakdown products may be assimilated by cells and/or tissues.

4 Purpose and Principles

4.1 Purpose In this test, oral medical devices are implanted in animals for a certain period of time (such as 28 days, 90 days) to measure their effects on the experimental animals in order to determine Whether it has potential subacute or subchronic systemic toxic effects.

4.2 Test principles In the process of evaluating the systemic toxicity characteristics of oral medical devices, whether to conduct subacute or subchronic systemic toxicity tests for implantation is appropriate.

6 Local reaction test after implantation

GB/T 16886.11 Biological evaluation of medical devices Part

11 Systemic toxicity tests

GB/T 16886.12 Biological evaluation of medical devices Part

12 Sample preparation and reference materials

GB/T 16886 (all parts) Biological evaluation of medical devices