Biocompatibility Evaluation Report

Product: HeartLink Patch Platform

Device Category: Surface contacting skin, prolonged contact greater than 24 hours and less than 30 days

Status: Non-sterile wearable ECG patch

1. Purpose

This report documents the biological evaluation of patient-contacting materials used in the HeartLink Patch Platform in accordance with ISO 10993 series standards and FDA guidance for medical devices.

2. Materials in Patient Contact

Component	Material	Contact Type
Adhesive layer	Acrylic medical adhesive	Skin
Backing film	Polyurethane film	Skin
Electrode gel	Hydrogel	Skin

3. Applicable Endpoints

Based on ISO 10993-1 for prolonged skin contact, the following endpoints were assessed:

- **Cytotoxicity**
- **Sensitization**
- **Irritation or intracutaneous reactivity**

4. Test Methods and Standards

Cytotoxicity: ISO 10993-5 using MEM elution method

Sensitization: ISO 10993-10 guinea pig maximization test

Irritation: ISO 10993-10 intracutaneous reactivity

5. Results Summary

Endpoint	Result	Acceptance
Cytotoxicity	No cytotoxic response	Pass
Sensitization	No sensitization observed	Pass
Irritation	No irritation response	Pass

6. Risk Assessment

No biologically relevant adverse effects were identified. Materials have a history of safe use in similar legally marketed devices. Extractables and leachables are not expected to pose additional risk.

7. Conclusion

The HeartLink Patch Platform meets biocompatibility requirements for its intended use and duration of skin contact. Residual biological risk is considered acceptable.

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