K963307

TARGET THERAPEUTICS

DEC 17 1996

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

CONTACT PERSON:
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DEVICE NAME:
Patient Return Electrode (PRE); Class II

DEVICE DESCRIPTION:
Target Therapeutics' Patient Return Electrode (PRE) is a single use, disposable, non-sterile electrode. The PRE is intended to be used as an alternative patient return electrode for Target Therapeutics GDC system (K951256 & K960705). A hypodermic needle is currently used as the patient return electrode. The PRE is applied to the skin on the patient's upper arm (deltoid). The PRE is being made available for patient comfort and has no effect on the safety or efficacy of the GDC system as functional testing indicates.

A small Prep pad is included with the PRE to exfoliate the skin prior to applying the PRE.

INDICATIONS FOR USE:
The Patient Return Electrode is indicated for use only with Target Therapeutics GDC System as the patient return electrode.

PREDICATE DEVICE:

Product Design:	Silver Sircuit™, Sentry Medical Products	K851522
Indications for Use:	Polyhesive® II, Valleylab, Inc	K861036
Functional Performance:	Hypodermic Needle, Target Therapeutics	K951256

TESTING in SUPPORT of SUBSTANTIAL EQUIVALENCE DETERMINATION:

The results of bench testing (Tensile Test, Impedance Test), animal studies, and biocompatibility testing support the substantial equivalence claims of the PRE for its intended use. Results of the bench testing, animal studies, and biocompatibility testing in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the PRE is substantially equivalent to the predicate devices.