

AUG 29 1988

L963240



**510 (k) Summary
Safety and Effectiveness**

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, California 90045-5597
Telephone Number: (213) 776-0180
Facsimile Number: (213) 776-0204
Contact Person: Edward M. Levine, Ph.D.
Director of Clinical Affairs
Date of Preparation: August 15, 1996
Device Name: IMMULITE ACTH Control Module
Trade: Device intended as an aid in monitoring the performance
of DPC's IMMULITE ACTH assay.
Catalog Number: LACCM
Classification: Class I device, 82-JJX (21 CFR 862.1660)
Manufacturer: Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597
Establishment Registration Number: DPC's Registration Number is 2017183
Description of Device: Quality Control Material
Intended Use of the Device: DPC's IMMULITE ACTH Control Module is an
assayed, bi-level control intended for use with DPC's
IMMULITE ACTH assay. It is intended strictly for in
vitro diagnostic use.
Clinical Studies: Not applicable
Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the device is safe and effective.

Edward M. Levine, Ph.D.
Director of Clinical Affairs

Date