

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

APR 10 1997

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

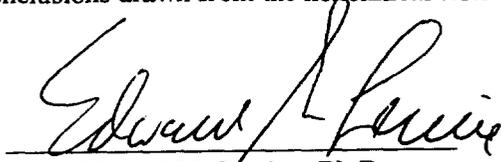
Name: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, California 90045-5597
Telephone Number: (213) 776-0180
Facsimile Number: (213) 776-0204
Contact Person: Edward M. Levine, Ph.D.
Director of Clinical Affairs
Date of Preparation: March 21, 1997
Device Name: IMMULITE® Thyroid Autoantibody Control
Module
Trade: Device intended as an aid in monitoring the performance
of the IMMULITE® Anti-TPO Ab assay.
Catalog Number: LAACM
Classification: Class I device, 75-JJX (21 CFR 862.1660)
Manufacturer: EURO/DPC Ltd., a wholly-owned subsidiary of DPC
Glyn Rhonwy
Llanberis, Gwynedd LL55 4EL
United Kingdom
(Manufacturing under a Quality System-ISO
9002/EN29002/BS 5750)
Sole U.S. Importer: Diagnostic Products Corporation (DPC)
5700 West 96th Street
Los Angeles, CA 90045-5597
**Establishment
Registration #:** EURO/DPC: Not Applicable
DPC: 2017183
**Substantially
Equivalent
Predicate Device:** DPC's PSA Control Module (K962975)
Description of Device: Quality Control Material
Intended Use of the Device: IMMULITE® Thyroid Autoantibody Control
Module is an assayed, bi-level control intended for use
with the IMMULITE® Anti-TPO Ab assay. It is
intended strictly for *in vitro* diagnostic use.
Clinical Studies: Not applicable

Diagnostic Products Corporation
IMMULITE® Thyroid Autoantibody Control Module
March 21, 1997

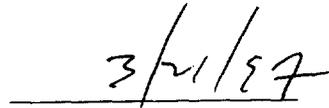
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Conclusion:

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