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Intelligent Product L.C.

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510(K) Summary

Submitter: Intelligent Product L. C.
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Date of Submission: Jan 10, 1996

Classification Name: Electronic Clinical Thermometer
Common/Usual Name: Pro-Flex
Proprietary Name: Pro-Flex, Digital Pacifier Thermometer

Legally Marketed Device to which Substantial Equivalence is claimed:
Digital Thermometer manufactured by Micro-Ideas Instruments Co. Ltd. (K844273)

Pro-Flex is a redesign of the traditional electronic thermometer with more convenient and comfortable features. It has flexible and soft probe make user comfortable in using. It also has insertion guide to prevent over insertion when use in rectal. The funnel shape of the probe is also fit the contour of baby's underarm so the tip of the probe will be in the same middle position of the armpit every time it is used.

The Pro-Flex is a safe device. It is contracted to be manufactured by ISO 9001 certified manufacturer, Micro Idea Instruments Co. Ltd. who also has some FDA registered Clinical Electronic Thermometer that are legally marketed in USA (Owner ID # 8020605). It is made to meet the ASTM 1112-86, "Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature". The materials that used on Pro-Flex include ABS plastic and the metal cap on the probe are the same materials on Micro Idea's thermometer which are legally marketed in US for a period of time already. The PVC flexible probe is also medical graded and certified by AlphaGary Corporation.

In conclusion, I believe that Pro-Flex is a well designed, quality and safe device. It is also substantially equivalent to the legally marketed device listed above. I hereby submit Pro-Flex for the 510(K) approval.

Sincerely,


Matthew Kho
President.