DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K183306

Device Name
GLUCOCARD® W onyx Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GLUCOCARD® W onyx Blood Glucose Monitoring System is comprised of GLUCOCARD® W onyx Blood Glucose Meter and disposable GLUCOCARD® W Blood Glucose Test Strips.

The GLUCOCARD® W onyx Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip or palm. Testing is done outside the body (in vitro diagnostic use). It is intended for use at home by persons with diabetes, as an aid in monitoring the effectiveness of a diabetes control program.

The GLUCOCARD® W onyx Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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