



SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K252757

B Applicant

CeQur SA

C Proprietary and Established Names

CeQur Simplicity™ On-Demand Insulin Delivery System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
OPP	Class II	880.5725 - Infusion pump	CH – Clinical Chemistry
LZG	Class II	880.5725 - Infusion pump	CH – Clinical Chemistry

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified

device **has not changed. This change was for extending the intended duration of wear from “up to 4 days” to “up to 7 days.”**

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.
5. A Design Control Activities Summary which includes:
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied. Verification and validation activities included an insulin-device compatibility study. Given the particular details of this device (e.g., a bolus-only device intended for adult use only), FDA determined that the risks related to loss of insulin efficacy resulting from extended wear duration could be adequately evaluated by in vitro bench testing alone, and therefore in vivo clinical testing was not required.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.