

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k091617

B. Purpose for Submission:

New device

C. Measurand:

Lidocaine

D. Type of Test:

Calibrator

E. Applicant:

Thermo Fisher Scientific

F. Proprietary and Established Names:

QMS Lidocaine Calibrators

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DLJ (Calibrator, secondary)	Class II	21 CFR§ 862.3200	Toxicology (91)

H. Intended Use:

1. Intended use(s):

See Indication(s) for Use below.

2. Indication(s) for use:

The QMS Lidocaine Calibrator set is intended for use in calibration of the QMS Lidocaine assay on the Hitachi 917 analyzer.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

QMS Lidocaine assay

I. Device Description:

The QMS Lidocaine Calibrator set is designed for the calibration of the QMS

Lidocaine assay for the quantitative determination of lidocaine in human serum on automated clinical chemistry analyzers. The QMS Lidocaine Calibrator set is a six-level set (0, 0.5, 1.0, 2.5, 5.0, 10 µg/mL) of single analyte (lidocaine) calibrators. This product contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested by FDA-approved methods and found to be nonreactive for HBsAg, anti-HIV 1/2, and anti-HCV.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Preciset TDM II Calibrators
2. Predicate 510(k) number(s):
K031856
3. Comparison with predicate:

Item	QMS Lidocaine Calibrators (Candidate device)	Roche Preciset TDM II Calibrators (Predicate device- k031856)
Intended Use	The QMS Lidocaine Calibrator set is intended for use in calibration of the QMS Lidocaine assay on the Hitachi 917 analyzer.	The Preciset TDM II Calibrators are designed for the calibration of the Roche assays for the quantitative determination of digitoxin, amikacin, lidocaine, N-acetylprocainamide, procainamide and quinidine in human serum and plasma on automated clinical chemistry analyzers
Components	6-level set of calibrators each containing lidocaine at the following concentrations: 0, 0.5, 1.0, 2.5, 5.0, 10 µg/mL	Mixture of 6 different drugs, including lidocaine at the following concentrations: 0, 0.5, 1.0, 2.5, 5.0, 10 µg/mL
Matrix	Human serum	Human serum

K. Standard/Guidance Document Referenced (if applicable):

None

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not Applicable

b. *Linearity/assay reportable range:*

Not Applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

The QMS Lidocaine Calibrators are traceable to United States Pharmacopeia (USP) lidocaine gravimetrically spiked into human serum.

Stability:

The stability of the calibrators is established through real time data. Testing is conducted at multiple time points and must pass pre-defined acceptance criteria. The sponsor's protocol and acceptance criteria are found to be acceptable. The unopened product refrigerated at 2 – 8 °C is stable for 12 months. The opened product is also stable for 12 months, refrigerated at 2 – 8 °C.

Value assignment:

Value assignments are based on an internal protocol using Master calibrators that have been validated by the predicate calibrators. The final bottle assignments are based on 25-50 replicates of each of the calibrator using the QMS lidocaine regents on the Hitachi 917 analyzer.

d. *Detection limit:*

Not Applicable

e. *Analytical specificity:*

Not Applicable

f. *Assay cut-off:*

Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable

- b. *Matrix comparison:*
Not Applicable
3. Clinical studies:
 - a. *Clinical Sensitivity:*
Not Applicable
 - b. *Clinical specificity:*
Not Applicable
 - c. Other clinical supportive data (when a. and b. are not applicable):
Not Applicable
4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:
Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.