

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

A. 510(k) Number:

B. Analyte:

Cannabinoid

C. Type of Test:

Cannabinoid calibrators.

D. Applicant:

Roche Diagnostics Corporation

E. Proprietary and Established Names:

Preciset DAT THC calibrator

Preciset DAT THC 20 calibrator

F. Regulatory Information:

1. Regulation section:
CFR § 862.3200, Clinical toxicology calibrator, Drug Specific
2. Classification:
Class II
3. Product Code:
DLJ,
4. Panel:
Toxicology (91)

G. Intended Use:

1. Intended Use(s):
Refer to the Indications for Use.
2. Indication(s) for use:
The Preciset DAT THC calibrators are designed for the calibration of the Roche assays for cannabinoids in human urine on automated clinical chemistry analyzers.
The Preciset DAT THC 20 calibrators are designed for the calibration of the Roche assays for cannabinoids in human urine on automated clinical chemistry analyzers.
3. Special condition for use statement(s):
Prescription Use Only
4. Special instrument Requirements:
Automated clinical chemistry analyzers

H. Device Description:

Preciset DAT THC calibrators contain 6 levels of Δ^9 – THC-COOH, prepared by the quantitative addition of drug to drug free urine. Target concentration levels included are 0, 20, 50, 100, and 300 ng/ml of cannabinoids with calibrators contained in bottles 1-6 at five ml for each level.

Preciset DAT THC calibrators contain 5 levels of Δ^9 – THC-COOH, prepared by the quantitative addition of drug to drug free urine. Target concentration levels included are 0, 10, 20, 40, and 100 ng/ml of cannabinoids with calibrators contained in bottles 1-5 at five ml for each level.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Abuscreen OnLine THC Calibration Pack 20 calibrators
2. Predicate K number(s):
K961726
3. Comparison with predicate:

Similarities & Differences		
Item	Device	Predicate
Intended Use	Intended for the calibration of the Roche assays for cannabinoids in human urine on automated clinical chemistry analyzers.	Intended for calibration of the Roche test system for the qualitative and semi-quantitative determination of cannabinoids in human urine on automated chemistry analyzers
Matrix	Human urine with added preservative	Human urine with added preservative
Calibrator levels	Preciset DAT THC Cannabinoida levels: 0, 20, 50, 100, 200, 300 ng/ml Preciset DAT THC 20 Cannabinoida levels: 0, 10, 20, 40, 100 ng/ml	Cannabinoida levels q, 20, 50, 100, 150 ng/ml

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

Roche Risk Management policy and ISO 14971:2000; Guidance for Industry - Abbreviated 510(k) Submissions for InVitro Calibrators

K. Test Principle: N/A**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:
 - a. *Precision/Reproducibility:* N/A
 - b. *Linearity/assay reportable range:* N/A

c. Traceability (controls, calibrators, or method): Drug concentrations in the Preciset DAT THC calibrators and Preciset DAT THC 20 calibrators are verified by gas chromatography/ mass spectroscopy (GC/MS).

d. Detection limit (functional sensitivity): N/A

e. Analytical specificity: N/A

f. Assay cut-off: N/A

2. Comparison studies:

a. Method comparison with predicate device: N/A

b. Matrix comparison: N/A

3. Clinical studies:

a. Clinical sensitivity: N/A

b. Clinical specificity: N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

M. Conclusion:

Based upon the information provided, I recommend that the Roche Preciset DAT THC calibrator & Preciset DAT THC 20 calibrator be found substantially equivalent with similar defined products based upon 21 CFR 862. § 862.3200, Clinical toxicology calibrator, Drug Specific