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Sysmex™

510(k) Summary of Safety and Effectiveness
Sysmex UF-Check™

510(k) Submitter: Sysmex Corporation
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Names of Device:

Trade Name:	UF-Check
Common Name:	Assayed Urinalysis Control
Classification Name:	Urinalysis quality control mixture

Predicate Device: Ret-Check (K900484)
SF-Check (K952245)

Description: UF-Check is a suspension of particles representing red blood cells, white blood cells, epithelial cells, casts, and bacteria in a liquid medium. Sysmex UF-Check is supplied in glass bottles containing 47 ml volumes. Three bottles - one of each level- are packaged in one box.

Intended Use: UF-Check™ is intended for use in the quality control of Sysmex UF-100™ automated urine analyzer. The Sysmex UF-100 is a *in vitro* medical device for use in urinalysis in clinical laboratories to replace microscopic review of normal and abnormal specimens and to flag specimens containing certain abnormalities.

Comparison with Predicate Device: Like Ret-Check, UF-Check is intended as an assayed control for an automated analyzer which uses the same flow cytometry technology. Like SF-Check, UF-Check is intended as an assayed control for an automated analyzer to perform like a five-part differential control. These controls are manufactured to contain measureable elements in a liquid medium. The UF-Check is different from the predicate products in the chemical composition of elements to simulate an urine sample rather than a blood sample.

Discussion of Tests and Test Results: Within Run Precision, Within Lot Precision, and Long Term Stability Studies were performed. Results were consistent and gave acceptable performance. UF-Check performs like a five-part differential control which when run in the QC mode gives values for the measurement of parameters. When run in the QC mode, all systems are checked for performance such as correct addition of dye, correct particle sizing, and correct enumeration of elements.

Conclusions Drawn from Tests: Study results show UF-Check to be consistently reproducible and stable for the entire product dating. UF-Check is a safe and effective urinalysis control when used as instructed in the product package insert.