Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Roche Diagnostics
Applicant Address	9115 Hague Rd. Indianapolis IN 46250 United States
Applicant Contact Telephone	317-385-2540
Applicant Contact	Mr. David Tribbett
Applicant Contact Email	david.tribbett@roche.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	Elecsys Syphilis, Elecsys Anti-CMV, cobas pro serology solution
Common Name	Syphilis Assay, CMV assay
Classification Name	test, donor, syphilis, antigens, treponemal; test, donor, cmv
Regulation Number	21 CFR 866.3830, 21 CFR 866.3175
Product Code(s)	MYR,MZE

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
BK241132	Elecsys Syphilis	MYR
BK241132	Elecsys Anti-CMV	MZE

Device Description Summary 21 CFR 807.92(a)(4)

This Special 510(k) submission describes the changes in software for the cobas pro Serology Solution. The changes are applicable for the Elecsys Syphilis assay and the Elecsys Anti-CMV assay. A device description for these assays are attached. Additionally, the cobas pro serology solution user guide is attached for a full description of the instrument and software.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Syphilis Assay: Elecsys Syphilis is an in vitro immunoassay for the qualitative detection of total antibodies (IgG and IgM) to Treponema pallidum in human serum and plasma. Elecsys Syphilis is intended to screen individual human donors, including volunteer donors of whole blood and blood components. This test is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens. The electrochemiluminescence immunoassay "ECLIA" is intended for use with the cobas pro serology solution equipped with cobas e 801 analytical unit.

Anti-CMV Assay: Elecsys Anti-CMV is an in vitro immunoassay for the qualitative detection of antibodies to Cytomegalovirus in human serum and plasma. Elecsys Anti-CMV is intended to screen individual human donors, including volunteer donors of whole blood, and blood components. This test is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens. The electrochemiluminescence immunoassay "ECLIA" is intended with cobas pro serology solution equipped with the cobas e 801 analytical unit.

cobas pro serology solution: The cobas pro serology solution is a combination of the cobas pro serology controller, cobas pro integrated solutions (cobas e 801 analytical units only) and applicable licensed blood screening assays. The system automates

electrochemiluminescence immunoassay test processing, result interpretation, and data management functions for screening of donations of whole blood and blood components using plasma or serum samples. The system is intended for use only with licensed blood screening assays in US donor screening laboratories and plasma fractionators. It is intended for use only by personnel who are trained in its operation. The cobas pro serology solution is intended to be used by trained laboratory technicians. Intended customers of the cobas pro serology controller used in combination with cobas pro integrated solutions (cobas e 801 analytical units only) are donor screening and plasma fractionation companies in the United States.

Indications for Use Comparison 21 CFR 807.92(a)(5)

There are no changes to indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

There are no changes to the assay reagents. New labeling for the assays has been included in this submission. This labeling contained a minor revision related to the use of the release controls. The primary purpose of this submission is due to software changes to the system. The software is being revised for the cobas pro analyzer system and the serology controller software application.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The changes reported here are minor software changes and no analytical testing nor clinical testing is required.