Bartels Inc.
THE DIAGNOSTICS DIVISION OF INTRACEL CORPORATION

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K9ꞷ2499

510(k) SUMMARY

Premarket Notification- Summary of Safety and Effectiveness
(per 21 CFR § 807.92(c))

Trade Name:	Zymmune™ Auto-Reader F Fluorescence Microplate Reader [with software]
Common/Usual Name:	Immunological Fluorometer
Classification Name:	Immunofluorometer equipment (per 21 CFR §866.4520)
Predicate Device:	Flow Laboratories Fluoroskan Reader

Device Description:
The Zymmune™ Auto-Reader F is a microplate reader that measures relative fluorescence signals from samples in a 96-well microplate. The Auto-Reader F is designed to be used with integrated software which collects and reports the measurements made by the microplate reader.

Intended Use:
In combination with approved microplate tests (such as the Bartels manufactured, Zymmune™ CD4/CD8 Cell monitoring assay kit) the Zymmune™ Auto-Reader F [with software] is intended for use for *in vitro* quantification and monitoring of T-cell levels.

Technological Comparison with Predicate Device
Similar to the predicate device, identified as the *Fluoroskan fluorescence reader*, the Zymmune™ Autoreader F reads relative fluroscence signal from samples in 96-well microplates. There are two differences between the Autoreader-F and the Fluoroskan:

1) The Autoreader is designed to read excitation an emission maxima consist with the measurement of fluorescein. The Fluoroskan can be operator-selected to read more than one wavelength, allowing its use in applications other than selectively reading the fluorescein signals associated with the Zymmune™ CD4/CD8 Cell Monitoring Kit.

2) The Autoreader-F includes an integrated software element that utilizes the algorithms appearing in the Zymmune™ CD4/CD8 Monitoring kit to convert the fluorescent signals into relative CD4 and CD8 levels in the specimen.

Non-Clinical Performance Comparison with Predicate Device

Non-clinical operational qualifications of the Autoreader-F were completed as part of a comprehensive software validation. The Autoreader-F was documented to meet operational criteria similar to that of the predicate device.

Clinical Performance Comparison with Predicate Device

A correlation study evaluated the Autoreader-F in comparison to the Fluoroskan fluorescence reader. 70 clinical samples were used to validate the performance of the Autoreader-F. Samples were tested on the Autoreader-F which provided the operator with CD4 and CD8 T-lymphocyte counts and a CD4/CD8 ratio. The same samples were tested using the predicate device. The predicate device provided fluorescent readings which were then manually converted into CD4 and CD8 T-lymphocyte cell counts using the algorithms provided in the CD4 and CD8 cell monitoring assay kit labeling (Bartels' manufactured, Zymmune™ CD4/CD8 Cell Monitoring Kit, FDA reviewed as 510(k) *K933878*).

Conclusion from Performance Comparison Data

T-lymphocyte counts obtained using the Autoreader-F with software and the Fluoroskan with manual calculations (tests run using Bartels' Zymmune™ CD4/CD8 Cell Monitoring Assay) were compared though linear regression analysis. Analysis showed excellent correlation between the two devices. Summary of results is as follows:

(n=70)	Slope	Intercept	Correlation Coefficient
CD4 T-lymphocyte	1.018	3.6	0.994
CD8 T-lymphocyte	1.035	-3.8	0.992
CD4/CD8 ratio	0.982	0	0.989

Contact

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