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13.0 510(k) Summary

13.1 General Information

Nellcor Puritan Bennett
10200 Valley View Road
Eden Prairie, MN 55344

Submitter's Name:	Chris Hadland
Phone:	(612) 941-3006
Fax Number:	(612) 829-5423
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13.2 Proprietary Name of the Device

Score Software (Models 4520 and 4530)

13.3 Common Name of the Device

Pulse Oximeter Display Software

13.4 Device Classification

Devices of this generic type have been classified as class II by the Respiratory Devices Panel. Devices of this type have a classification code of 74 DQA, Oximeter (21CFR 870.2700).

13.5 Intended Use

Score Software is an accessory to two NPB pulse oximeters. It is intended to provide clinicians with the ability to collect, edit, and analyze trend data recorded by a Nellcor Symphony™ N-3000 pulse oximeter or a Nellcor Puritan Bennett™ N-200 pulse oximeter. It provides general functions that are not intended to diagnose any specific disease.

13.6 Predicate Device Equivalence

We are claiming substantial equivalence Nellcor P200S Thermal Printer first described in cleared 510(k) K913695

13.7 Device Description

Depending on which pulse oximeter the clinician uses and how the pulse oximeter parameters are set, the *Score Software* analysis function provides the following results:

- Pulse rate and standard deviation
- SpO_2 analysis and study information
- Alarm and desaturation event log (only N-3000 records alarm data)
- Pulse search and motion indication (N-3000 only)
- Percentage of time spent in motion (N-3000 only)
- Percentage of time spent in pulse search (N-3000 only)

Analysis results are intended to be used within the context of the fully disclosed trend data.
Score Software retrieves data from certain pulse oximeters such as the Nellcor Puritan Bennett Models N-200 and N-3000, displays recorded data, analyzes the data, and generates a report for the user to review. The report includes both raw wave forms and summary statistics such as number desaturations. The event definitions are defined by the user.

13.8 Comparison of Technologic Characteristics

Score Software produces reports that contain similar information and have a similar report format to the P200S predicate device. Score is different than the P200S Thermal Printer in that the P200S Thermal Printer is a self-contained instrument with intrinsic ability to perform all functions using its internal circuitry, microprocessing power and hardware capability, while *Score Software* is designed to run on standard IBM compatible computers using a Windows operating system. *Score* relies upon the computer microprocessor and standard printers driven by Windows print drivers.

13.9 Summary of Performance Testing

13.9 Testing was performed to confirm that *Score Software* is capable of meeting its intended functional requirements. *Score Software* passed all tests.

13.9 All software was tested in compliance with the *Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) review* published by the Office of Device Evaluation within the CDRH. Score passed all tests.

13.10 Conclusions

We conclude that the *Score Software* meets its stated performance specifications and criteria outlined in the Reviewers Guidance publication referenced above. We conclude that *Score Software* will operate safely in its intended environment and be effective in fulfilling its intended use. The safety and effectiveness of *Score Software* features are as safe and effective as the respective features provided on the predicate device.