



Food and Drug Administration  
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March 31, 2017

EnsoData, Inc.  
% Seth Mailhot  
Partner  
Michael Best & Friedrich, LLP  
601 Pennsylvania Ave, NW Suite 700 South  
Washington, District of Columbia 20004

Re: K162627  
Trade/Device Name: EnsoSleep  
Regulation Number: 21 CFR 882.1400  
Regulation Name: Electroencephalograph  
Regulatory Class: Class II  
Product Code: OLZ  
Dated: March 27, 2017  
Received: March 29, 2017

Dear Mr. Mailhot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Michael J. Hoffmann -S**

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K162627

Device Name

EnsoSleep

Indications for Use (Describe)

EnsoSleep is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory related sleep disorders in adults only. EnsoSleep is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including obstructive apneas. All automatically scored events are subject to verification by a qualified clinician. Central apneas, mixed apneas, and hypopneas must be manually marked within records.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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# 510(k) Summary

**Submitted by:** EnsoData, Inc.  
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Madison, WI, 53703  
**Telephone:** (608) 509-4704  
**Contact Name:** Chris Fernandez, Co-founder and CEO  
**Date Submitted:** August 13, 2016  
**Trade Name:** EnsoSleep  
**Common Name:** Automatic Event Detection Software for Polysomnograph with Electroencephalograph  
**Product Code:** OLZ  
**Regulatory Class:** II (21 C.F.R. 882.1400)  
**Review Panel:** Neurology  
**Predicate Device:** Advanced Brain Monitoring, Inc. Sleep Profiler (K153412)  
**Reference Device:** Younes Sleep Technologies MICHELE Sleep Scoring System (K112102)

## Device Description:

EnsoSleep is a software application that analyzes previously recorded physiological signals obtained during sleep. The EnsoSleep software can analyze any EDF or EDF+ files.

Automated algorithms are applied to the raw signals in order to derive additional signals and interpret the raw and derived signal information. The software automates recognition of:

### Sleep Stage Events

- Wake
- Stage N1
- Stage N2
- Stage N3
- Stage REM

### Respiratory Events

- Sleep disordered breathing (apneas and hypopneas)
- Apneas detected with airflow signal are classified as obstructive apnea (OSA), and can be edited to be central or mixed apneas
- Sleep disordered breathing events not detected to be apneas are marked as hypopnea
- Central apneas, mixed apneas, and hypopneas must be manually marked within records

### Arousal Events

- Arousals

### Movement Events

- Periodic Leg Movements during Sleep (PLMS)

The EnsoSleep software can be used as a stand-alone application for use on Microsoft Windows 7 & 8 operating system platforms. All processing, scoring, and analysis of signal data occurs on the EnsoSleep cloud servers.

## Indications for Use:

EnsoSleep is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory related sleep disorders in adults only. EnsoSleep is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including obstructive apneas. All automatically scored events are subject to verification by a qualified clinician. Central apneas, mixed apneas, and hypopneas must be manually marked within records.

## Determination of Substantial Equivalence:

### Summary of Technology:

The EnsoSleep software-only device is similar in intended use and functionality to the Sleep Profiler (K153412) by Advanced Brain Monitoring, Inc. and Younes Sleep Technologies MICHELE Sleep Scoring System (K112102) electroencephalograph analysis software programs. The EnsoSleep device is similar with respect to indications for use and physical characteristics to the predicate device and

reference device in terms of 510(k) substantial equivalency.

Based on analysis and comparison of technological characteristics and features between EnsoSleep and the predicate device and reference device, EnsoSleep is determined to have the same technological characteristics as the predicate and reference devices, and does not raise different questions of safety or efficacy as demonstrated by the device design. EnsoSleep uses the same fundamental technology as the legally marketed predicate device and reference device; automated algorithms are applied to raw signals in order to derive additional signals and interpret raw and derived signal information. Each of the EnsoSleep, Sleep Profiler (K153412), and MICHELE Sleep Scoring System (K112102) devices include as features the ability for full disclosure recording of derived signals and automated analyses to be visually inspected and edited prior to the results being integrated into one of several sleep study report data formats. Each of the EnsoSleep, Sleep Profiler (K153412), and MICHELE Sleep Scoring System (K112102) devices base the automatic scoring of physiological events on the American Academy of Sleep Medicine scoring rules, guidelines, definitions, and procedures. Additionally, the EnsoSleep predicate device Sleep Profiler (K153412, K130007, K120450), in an earlier cleared version of the device, utilized MICHELE Sleep Scoring (K112102) as its own predicate device for establishing substantial equivalence based on performance validation testing comparisons.

Both the predicate Sleep Profiler (K153412) and EnsoSleep devices can be used as a stand-alone software application with a user interface delivered on the Microsoft Windows 7 or 8 operating system platforms, and automatically reject periods of poor EEG signal quality. The following features were not included in the EnsoSleep application as they were deemed unnecessary based on end-user feedback and/or the fact that they are not requirements under the current AASM guidelines: detection of heart rate, head position, snoring levels, head movements, and respiratory event related apneas (RERAs); disease management comments; two-night reports. The chosen EnsoSleep design and implementation features scoring, efficiency, reliability, and security improvements over Sleep Profiler (K153412) and MICHELE Sleep Scoring System (K112102). EnsoSleep provides more comprehensive coverage of the event types specified for scoring by the AASM Manual for Scoring and Associated Events recommendations than the Sleep Profiler (K153412) device by automatically scoring leg movement events in addition to the sleep disordered breathing, obstructive apnea, arousal, and sleep staging event automated scoring functionality supported by both the predicate and reference devices. Both the Sleep Profiler (K153412) predicate device and EnsoSleep classify each apnea as obstructive, each non-apnea sleep disordered breathing event as a hypopnea (excluding RERAs), and enable apneas to be edited and manually marked to be central or mixed apneas within records.

EnsoSleep differs from Sleep Profiler (K153412) and MICHELE Sleep Scoring System (K112102) in that EnsoSleep automates the initiation, upload, scoring, and download of studies, enabling a user experience that is optimized for efficiency and fast automated analysis prior to the required user over-read of EnsoSleep scoring. Furthermore, the high-performance specifications of the EnsoSleep Processing Platform enables throughput efficiency and scalability, as the speed by which a study processes is dependent on the number of distributed servers, parallel computer processor(s), and the amount of RAM. EnsoSleep improves networking reliability through fault-tolerant network protocols with automatic connection-recovery that are robust to poor or interrupted network conditions. Finally, EnsoSleep provides cybersecurity improvements over the predicate Sleep Profiler (K153412) and MICHELE Sleep Scoring System (K112102) with verified authentication, authorization, and access controls; cryptographic and checksum controls including end-to-end encryption; secure software distribution mechanisms and controls; intrusion detection systems and vulnerability scanning; and other network, systems, and database controls.

#### **Summary of Non-Clinical Tests:**

Support for the substantial equivalence of EnsoSleep was provided by risk management and software testing. Both EnsoSleep and Sleep Profiler (K153412) conduct and document verification, validation, and performance testing as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The EnsoSleep software has been thoroughly tested through verification of specifications. One or more verification tests are provided for each requirement specified with detailed protocols, objective pass/fail criteria, and clearly documented test executions with results. Detailed plans and protocols were developed prospectively for system level, performance, and usability validation testing. Validation testing was conducted with qualified clinical and non-clinical users, with objective pass/fail criteria, ability to provide comments, and with all testing reports and results documented for review.

#### **Summary of Clinical Tests:**

Substantial equivalence was also established through a testing protocol that used clinical polysomnography (PSG) data to evaluate the performance of EnsoSleep. Clinical performance testing was completed by evaluating EnsoSleep device performance using a cross-sectional experimental design on a representative N=72 subject sample of retrospective clinical PSG data. First, the intended use population, study population, conditions of interest, designated comparative reference, designated comparative benchmarks, and experimental endpoints were defined. Upon applying predefined selection controls, a statistically representative sample of the defined intended use and user population sample consisting of N=72 subjects were selected from a N=823 archived collection of retrospective diagnostic clinical PSG data collected from an AASM Accredited Sleep Testing Facility. Same as the predicate and reference devices respectively, the study population was then sent to a clinical testing laboratory where each PSG was manually scored by three (3) independent registered sleep technologists (RPSGT) that met all acquisition, scoring-bind, and rater quality certification controls. A designated comparative reference was constructed using 2/3 Majority Scoring to evaluate the EnsoSleep device performance versus the predicate Sleep Profiler and MICHELE device performance. Objective performance benchmarks and acceptance criteria of positive percent agreement (PA), negative percent agreement (NA), and overall percent agreement (OA) were predefined competitively based on analysis of sleep staging event detection and diagnostic agreement performance reported in the predicate device 510(k) documentation. The predicate device did not report clinical testing results for sleep disordered breathing, arousal, and leg movement event detection agreement performance, and therefore the reference device clinical performance and 510(k) documentation were used to facilitate a valid comparison. EnsoSleep device performance was evaluated using the defined cross-sectional experimental design, statistical methodology, and controls, across the following three (3) experimental endpoints:

1. Endpoint 1: As EnsoSleep is intended to assist clinicians with the assessment of sleep quality, performance of device sleep scoring must be validated. For Endpoint 1, EnsoData evaluated a performance goal comparing the predicate device Sleep Profiler (K153412) PA, NA, and OA sleep staging performance, and the bootstrapped point estimate of median performance for EnsoSleep sleep staging PA, NA, and OA versus a 2/3 Majority Scoring reference.

2. Endpoint 2: As EnsoSleep is intended to assist clinicians with the scoring sleep disordered breathing events used in diagnostic evaluation, device performance for diagnosing sleep apnea must be validated. For Endpoint 2, EnsoData evaluated a performance goal comparing the predicate device Sleep Profiler (K153412) PA, NA, and OA diagnostic agreement performance, and the bootstrapped point estimate of median performance for EnsoSleep diagnostic agreement PA, NA, and OA versus a 2/3 Majority Scoring reference.
3. Endpoint 3: As EnsoSleep is intended to analyze physiological signals and automatically score sleep study results, including detection of sleep disordered breathing events, apnea events, arousal events, and leg movement events, device performance for detecting each event type must be validated. For Endpoint 3, EnsoData evaluated a performance goal comparing the reference device MICHELE Sleep Scoring System (K112102) PA, NA, and OA event detection performance, and the bootstrapped point estimate of median performance for EnsoSleep event detection PA, NA, and OA versus a 2/3 Majority Scoring reference.

The final experimental results and statistical analysis were reported for each endpoint. In total, bootstrapped point-estimates for median PA, NA, OA performance with 95% percentile bootstrap confidence intervals (R=1000 resamples) were calculated by overall-epochs versus 2/3 Majority Scoring in event detection experiments evaluating Wake, N1, N2, N3, REM, SDB, Apnea, OSA, Arousal, and Leg Movement event detection performance respectively. Furthermore, EnsoSleep device diagnostic agreement was evaluated versus 2/3 Majority on both mild and moderate sleep apnea diagnostic thresholds by computing the overall and REM-only apnea-hypopnea index (AHI). In total, bootstrapped point-estimates for median PA, NA, OA, performance with 95% percentile bootstrap confidence intervals (R=1000 resamples) and likelihood ratio pairs were computed in diagnostic agreement experiments evaluating overall-mild AHI, overall-moderate AHI, REM-mild AHI, and REM-moderate AHI. The final experimental results and statistical analysis are summarized for each endpoint in Table 1, Table 2, and Table 3 below.

Table 1 shows the EnsoSleep and Sleep Profiler (K153412) clinical performance results compared for Endpoint 1, sleep staging. For all sleep staging event types evaluated in Endpoint 1, EnsoSleep PA, NA, and OA performance was observed to show no statistically significant differences or was observed to be statistically significantly greater in all comparisons relative to the predicate device. There were no cases where predicate device Wake, N1, N2, N3, REM, or Total Staging performance was statistically significantly greater than EnsoSleep event detection performance (i.e. the predicate device point estimate for PA, NA, and OA were never higher than EnsoSleep PA, NA, and OA 95% CI upper bounds). The results confirm EnsoSleep achieves clinical performance for sleep staging positive, negative, and overall agreement that is substantially equivalent to the Sleep Profiler positive, negative, and overall agreement across all sleep stages.

Table 1: Sleep Staging Clinical Performance Comparisons		Overall-Epochs EnsoSleep vs 2/3 Majority Sleep Staging Performance				Overall-Epochs Sleep Profiler (K153412) vs 2/3 Majority Sleep Staging Performance			
		(N=72 subjects, 59719 epochs)	Bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=1000 resamples)			(N=43 subjects, 31361 epochs)	Point-estimate of Percent Agreement (%)		
			Total Epochs	Positive Agreement (PA)	Negative Agreement (NA)		Overall Agreement (OA)	Total Epochs	Positive Agreement (PA)
Overall-epochs assigned by 2/3 Majority Scoring	Wake	17459	86% (82%, 88%)	97% (95%, 98%)	94% (92%, 95%)	7424	73%	94%	89%
	N1	3293	41% (33%, 48%)	94% (93%, 96%)	91% (90%, 93%)	1752	25%	93%	89%
	N2	26839	77% (73%, 81%)	87% (85%, 90%)	83% (80%, 85%)	12582	77%	84%	81%
	N3	5587	81% (74%, 88%)	93% (91%, 95%)	92% (90%, 94%)	4704	76%	94%	91%
	REM	6541	79% (72%, 84%)	99% (98%, 99%)	96% (96%, 97%)	3749	74%	97%	95%
	Total	59719	78% (77%, 80%)	95% (94%, 95%)	91% (91%, 92%)	31361	73%	93%	87%
	None	1432	-	-	-	1150	-	-	-

Table 2 shows the EnsoSleep and Sleep Profiler (K153412) clinical performance results compared for Endpoint 2, sleep apnea diagnostic agreement. For all diagnostic agreement experiments evaluated in Endpoint 2, mild-REM, moderate-overall, and moderate-REM, EnsoSleep PA and NA performance were observed to show no statistically significant differences compared to predicate device performance (e.g. the two-sided 95% percentile bootstrap confidence interval bounds contained the predicate device point estimates for PA and NA in all cases). The only statistically significant difference observed was for overall-mild PA, with a 2% difference in the EnsoSleep CI upper bound and Sleep Profiler point estimate (91% [82%,98%] vs. 100%) and no statistically significant differences in overall-mild NA. Furthermore, the point estimate of EnsoSleep PA, NA, and OA performance exceeded, were equivalent to, or were within 10% of the predicate device PA and NA point estimates for all comparisons. The EnsoSleep positive likelihood ratios were observed to be above 3.5 for overall/REM-mild and above 5.0 for overall/REM-moderate in all diagnostic agreement experiments, similarly exceeding the performance goal targeted by Sleep Profiler (K153412) in the predicate device 510(k) documentation. The results confirm EnsoSleep achieves clinical performance for positive and negative sleep apnea diagnostic agreement that is substantially equivalent to the Sleep Profiler positive and negative agreement across all mild-overall, mild-REM, moderate-overall, and moderate-REM comparisons.

Table 2: Sleep Apnea Diagnostic Agreement Clinical Performance Comparisons	Per-Patient EnsoSleep vs 2/3 Majority Sleep Apnea Diagnostic Agreement				Per-Patient Sleep Profiler (K153412) vs 2/3 Majority Sleep Apnea Diagnostic Agreement			
	EnsoSleep		EnsoSleep REM		Sleep Profiler		Sleep Profiler REM	
	AHI >= 5	AHI >= 15	AHI >= 5	AHI >= 15	AHI >= 5	AHI >= 15	AHI >= 5	AHI >= 15
EnsoSleep bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=1000 resamples), Sleep Profiler point-estimate of Percent Agreement (%), and likelihood ratio pairs								
Sample size (N)	72	72	72	72	60	60	40	40
Positive Agreement (PA)	91% (82%, 98%)	95% (83%, 100%)	83% (72%, 94%)	79% (56%, 94%)	100%	100%	84%	73%
Negative Agreement (NA)	76% (61%, 90%)	98% (94%, 100%)	89% (79%, 97%)	96% (90%, 100%)	85%	97%	90%	96%
Overall Agreement (OA)	85% (77%, 92%)	97% (93%, 100%)	86% (79%, 93%)	92% (85%, 97%)	N/A	N/A	N/A	N/A
Likelihood ratio (+)	3.76	52.25	7.71	22.00	6.67	9.50	8.84	18.33
Likelihood ratio (-)	0.12	0.05	0.19	0.22	0.00	0.00	0.00	0.28

Table 3 shows the EnsoSleep and MICHELE Sleep Scoring (K112102) clinical performance results compared for Endpoint 3, event detection agreement. The MICHELE Sleep Scoring performance testing did not calculate OA for individual event types in the same way as EnsoSleep, and as such only PA and NA comparisons were made to avoid biased performance evaluation. For all event detection experiments including SDB, OSA, Arousal, and Leg Movement event types, the point-estimates of EnsoSleep PA and NA event detection performance exceeded, were equivalent to, or were within 10% of the reference device PA and NA performance, with statistically significant differences observed in a minority of cases. On the basis that EnsoSleep met or exceeded objective PA and NA performance goals for these event types in all comparisons, and the reference device did not provide information to adequately compare the statistical significance of results (i.e. two-sided confidence intervals for point-estimates of agreement were not reported), EnsoSleep is considered substantially equivalent to the reference device SDB, Apnea, OSA, Arousal, and Leg Movement event detection performance.

Table 3: Event Detection Clinical Performance Comparisons		Overall-Epochs EnsoSleep vs 2/3 Majority Event Detection Performance				Overall-Epochs MICHELE (K112102) vs 2/3 Majority Event Detection Performance			
		(N=72 subjects, 59719 epochs)	Bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=1000 resamples)			(N=30 subjects, 24987 epochs)	Weighted average of Positive and Negative Percent Agreement (%) point-estimates and Overall Percent Agreement (%) point-estimate		
			Total Epochs	Positive Agreement (PA)	Negative Agreement (NA)		Overall Agreement (OA)	Total Epochs	Positive Agreement (PA)
Overall-epochs assigned by 2/3 Majority Scoring	Sleep Disordered Breathing Events (apneas and hypopneas)	4705	67% (58%, 75%)	93% (92%, 94%)	91% (90%, 92%)	2439	75.5%	98.1%	93.0%
	Apnea Events	1690	56% (41%, 70%)	96% (96%, 97%)	95% (95%, 96%)	750	N/A	N/A	N/A
	Obstructive Apnea Events	1066	53% (35%, 71%)	97% (96%, 97%)	96% (95%, 97%)	359	55.9%	99.3%	N/A
	Arousal Events	7686	66% (61%, 71%)	90% (88%, 91%)	87% (85%, 88%)	2278	60.0%	94.1%	89.9%
	Leg Movement Events	5796	71% (60%, 80%)	90% (89%, 92%)	89% (87%, 90%)	1714	78.4%	97.6%	95.7%

In summary, performance test results demonstrated that EnsoSleep achieves automated sleep staging event detection, sleep apnea diagnostic agreement, and sleep disordered breathing, apnea, obstructive apnea, arousal, and leg movement event detection agreement that is substantially equivalent to the predicate device Sleep Profiler (K153412) performance and reference device MICHELE (K153412) performance for all comparisons in all endpoints analyzed respectively. The EnsoSleep performance validation testing demonstrates the safety and effectiveness of EnsoSleep when used for the defined indications for use and demonstrates that the device performs as well as the legally marketed predicate Sleep Profiler (K153412) and reference MICHELE Sleep Scoring (K112102).

#### Conclusion:

Non-Clinical and Clinical verification, validation, and performance testing was conducted in accordance with FDA guidance recommendations to confirm the device design met all specifications, user needs, and was acceptable to qualified clinical and non-clinical users. EnsoSleep has passed all of the aforementioned Verification and Validation tests and provided Clinical Performance testing results with a library clinical dataset in order to demonstrate safety or effectiveness. It is therefore concluded that EnsoSleep is substantially equivalent to the predicate device.