January 31, 2018

Odstock Medical Ltd
Steven Crook
Quality and Regulatory Manager
Salisbury District Hospital
Salisbury, Wiltshire, SP2 8BJ UK

Re: K171396
Trade/Device Name: ODFS Pace XL
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: October 27, 2017
Received: November 13, 2017

Dear Steven Crook:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K171396

Device Name
ODFS® Pace XL

Indications for Use *(Describe)*
The ODFS® Pace XL is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow.

The ODFS® Pace XL is a medical device and should only be used under medical supervision for the treatment of dropped foot following an upper motor neuron injury.

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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THROUGH TECHNOLOGY

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**510(k) Summary (Traditional format)**
**For the**
**ODFS® Pace XL**

**Sponsor/Owner/Manufacturer**

Odstock Medical Limited
Laing Building
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ
United Kingdom

Odstock Medical Ltd is a Registered Establishment, number: 3005344585

| | |
|---|---|
| Contact person: | Steven Crook, Quality and Regulatory Manager |
| Telephone: | 0044 1722 439541 |
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Date prepared 30th January 2018

## 510(k) Summary for the ODFS® PACE XL Dropped Foot Stimulator

### DEVICE NAME

| | |
|---|---|
| Trade/Proprietary Name: | ODFS® Pace XL |
| Common/Usual Name: | Dropped foot stimulator |
| Classification Name: | External Functional Neuromuscular Stimulator (FES)<br>Powered Muscle Stimulator (NMES) |
| Classification No. | 21 CFR 882.5810 |
| Classification Code: | Class II |
| Product Codes: | GZI and IPF |

### Predicate Devices

| Predicate Device | K number | Comment |
|---|---|---|
| ODFS® Pace | K102115 | Odstock Medical Ltd |
| ODFS® III V6.2 | K050991 | Odstock Medical Ltd (transferred from Salisbury District Hospital) |

### Device Description

The ODFS® Pace XL is an external functional neuromuscular stimulator. It consists of a small, body worn, battery powered, single channel stimulator which is triggered by a footswitch worn in the shoe. The footswitch options are:

1. Shoe insole incorporating wireless transceiver which provides wireless triggering
2. 'Out of shoe' wireless transceiver with 'in shoe' heel switch. Provides wireless triggering.
3. Wired 'in shoe' heel switch for where 1 & 2 are not appropriate or to cover an emergency, e.g. loss of battery power in wireless accessory.

The triggering element and detection is the same across all options and option 3 is common to the ODFS® Pace (predicate device).

Electrical pulses are generated by the device in order to stimulate muscle contractions in the lower limb. (Neuromuscular stimulation) Triggering with a footswitch permits the stimulation to be varied according to the gait of the user. Stimulation produces contraction of the appropriate muscles to cause dorsiflexion of the ankle in individuals who have impaired or absent ability to pick up their foot during walking as a result of a neurological injury. This paralysis affecting the foot is commonly known as 'drop foot' or 'dropped foot'.

The electrical stimulation is delivered via self adhesive skin surface electrodes. The electrodes may be flexibly placed according to the optimum response of the patient but typically are located over the common peroneal nerve as it passes near the head of the fibula. The user may be offered the below knee ODFS® Leg Cuff accessory as aid to locating electrodes repeatedly day to day. An additional option is to mount the ODFS® Pace XL upon the ODFS® Leg Cuff.

For individuals presenting with weakness and/or spasticity a muscle stimulation exercise program can be delivered by the ODFS® Pace XL. In this case the footswitch trigger is not used and the ODFS® Pace functions as a powered muscle stimulator. A clinician would determine the need for this application which can be enabled from a setup option in the ODFS® Pace XL. (Default is to have the exercise disabled)

## Intended Use

The ODFS® Pace XL is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow.

The ODFS® Pace XL is a medical device and should only be used under medical supervision for the treatment of dropped foot following an upper motor neuron injury.

## Technological Characteristics and Substantial Equivalence

The technological characteristics of the ODFS® Pace XL and predicate devices are tabulated below. All the devices are battery powered and deliver electrical stimulation pulses of similar waveform, pulse width and frequency. The ODFS® Pace is a development of the ODFS® III v6.2 and therefore has identical indications for use as an FES device, as does the ODFS® Pace XL. The ODFS® Pace XL has internal software (firmware) version 1.3 whereas the cleared ODFS® Pace has firmware version 1.2. Internal circuitry is unchanged apart from addition of the wireless transceiver expansion circuit.

The footswitch contains a force sensitive resistor within a thin proprietary package. As a wired footswitch this may be located flexibly within the shoe. Generally the position is under the heel. Two wireless footswitch versions are available for the ODFS® Pace XL.

An insole, which has a fixed position for the switch element, fits inside the full length of the shoe. The thickness is of the order of 6mm and a non-functioning equivalent insole is supplied for the other shoe. The thickness of the insole is a limitation which prevents the use in certain shoes.

The second wireless version (OML LINQ™ ) makes use of the thin wired footswitch with a shortened cable. This is connected to a small out of shoe transceiver that can be flexibly located with a clip or retained in a sock. Extensive performance testing was part of the wireless footswitch development to ensure equivalence to the wired version.

## 5.6 Technological Characteristics and Substantial Equivalence - Table

| **Feature** | **ODFS® Pace XL** | **ODFS® Pace** | **ODFS® III v6.2** |
|---|---|---|---|
| **Firmware** | **V1.3** | **V1.2** | **Not applicable** |
| Waveform | Biphasic (symmetrical and balanced asymmetrical) | Biphasic (symmetrical and balanced asymmetrical) | Biphasic (symmetrical and balanced asymmetrical) |
| Pulsewidth | 0µs - 360µs (±10%) according to patient selection (3.6 µs steps) | 0µs - 360µs (±10%) according to patient selection (3.6 µs steps) | 7µs - 365µ (±10%) according to patient selection |
| Frequency | Default is 40Hz.<br>20 – 60 Hz in 5Hz steps available | Default is 40Hz.<br>20 – 60 Hz in 5Hz steps available | 40Hz ± 10% |
| Indications for use | The ODFS® Pace XL is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow.<br><br>As a NMS/NMES device: relaxation of muscle spasm; prevention or retardation of disuse atrophy; increasing local blood circulation; muscle re-education; maintaining or increasing range of motion. | The ODFS® Pace is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow.<br><br>As a NMS/NMES device: relaxation of muscle spasm; prevention or retardation of disuse atrophy; increasing local blood circulation; muscle re-education; maintaining or increasing range of motion. | To provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. By detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait by flexing the foot of persons who have lost or impaired function. There may be additional benefits from FES such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow. |
| Accessories | Wireless heel switch (2 versions), wired heel switch. Electrode locator cuff (Leg Cuff) | Heel switch (wired) | Heel switch (wired) |
| Electrode size & shape. | 5cm x 5cm | 5cm x 5cm | 5cm x 5cm |

## 5.7 Performance testing

The ODFS® Pace XL system has been subjected to testing to verify that the device meets its functional and output specifications. Production units pass functional testing of stimulator controls, settings and indicators, stimulus output and timing, footswitch operation, and power consumption.
Parameters measured under the conditions specified in *FDA Guidance Document for Powered Muscle Stimulator 510(k)s* are included in the ODFS® Pace 510(k) submission. These are identical for the ODFS® Pace XL and reproduced below. (Appendix 1)

Wireless footswitch production models have been tested to functionally perform as reliably and effectively as the wired version.

In addition to functional and operational performance testing the ODFS® Pace XL passed the applicable requirements of the following standards:

- ISO 60601-1-1:2006 Medical Electrical Equipment – General requirements for basic safety and essential performance.
    - ODFS Pace XL is electrically identical to the ODFS Pace in respect of the pulse delivery to the patient. A wireless transceiver circuit is additional and activated when a wireless footswitch accessory is in use.
    - Performance is verified with wired and wireless footswitches.

- ISO 60601-1-2:2007 Medical Electrical Equipment – General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility – Requirements and tests
    - ODFS Pace XL tested by third party – report supplied for inclusion in submission.
    - Wireless accessories are also tested and included in the submitted report.

- ISO 60601-2-10:2001 Medical electrical equipment. Particular requirements for the safety of nerve and muscle stimulators
    - ODFS Pace XL outputs etc. unchanged from ODFS Pace

Based on the information provided above the ODFS® Pace XL is substantially equivalent to legally marketed predicate devices.

Performance data is included on the next page.

Performance data

| **Feature** | **ODFS® Pace (cleared device)**<br>**ODFS® Pace XL (modification)** | **ODFS III (cleared device)** |
|---|---|---|
| Waveform | Biphasic (symmetrical and balanced asymmetrical) | Biphasic (symmetrical and balanced asymmetrical) |
| Shape | (Quasi)-rectangular | (Quasi)-rectangular |
| Maximum Output Voltage (+/-10%) | 86V peak; 8Vrms @ 500R<br>104V peak; 11.5Vrms @1k<br>125V peak; 14Vrms @ 2K<br>140V peak; 18Vrms @10K | 85V peak; 9Vrms @500R<br>115V peak; 11Vrms @1K<br>130Vpeak;13Vrms@2K<br>150V peak; 14Vrms@10K |
| Maximum output current (+/-10%) | 172mA @ 500R<br>62mA @ 2K<br>14mA @ 10K | 170mA peak:18mArms@500R<br>155mA peak:11mArms@1K<br>65mApeak:6.5mArms@2K<br>15mA peak:1.4mArms@10K |
| Pulse width | 0 – 360 microseconds (+/- 10%) in 3.6 microsecond steps | 7 to 360 microseconds, clinician selectable |
| Frequency | 20Hz to 60Hz in 5Hz steps (+/-10%) | 40Hz (+/- 4Hz) |
| Interferential modes:<br>Beat frequency | Not Applicable | Not Applicable |
| For multiphasic waveforms only<br>Symmetrical phases<br>Phase duration | Yes – symmetrical mode<br><br>360 (+/- 20) microseconds | Yes – symmetrical mode<br><br>365 (+/- 20) microseconds |
| Net charge (µC per pulse) | 0µC | 0µC |
| Max phase charge | 50µC @ 500R | 50µC @ 500R |
| Maximum current density [1] | 0.9mArms/$cm^2$ @ 500R<br>0.6mArms/$cm^2$ @ 1K | 0.9mArms/cm2 @ 500R<br>0.6mArms/cm2 @ 1K |
| Maximum power density (mW/cm2) | 3.9mW/cm2 @ 500R<br>3.2mW/cm2 @ 1K | 3.9mW/cm2 @ 500R<br>3.2mW/cm2 @ 1K |
| Burst Mode (i.e. pulse trains)<br>a. pulses per burst<br>b. Bursts per second<br>c. Burst duration (seconds)<br>d. Duty Cycle | NA – Continuous pulse train during swing phase | NA – Continuous pulse train during swing phase |
| ON Time (seconds) | 0.2 (+/- 0.02) seconds to 6(+/-) seconds as adjusted by clinician | 0.2 (+/- 0.02) seconds to 6(+/-) seconds as adjusted by clinician |
| OFF Time (seconds) | Varies with gait cadence of patient | Varies with gait cadence of patient |
| Additional Features (if applicable) | Pulse train is initiated by heel switch (wired or wireless(XL)) in patient's shoe. Pulse train is programmed by clinician for fixed duration or terminated after footswitch contact. | Pulse train is initiated by heel switch(wired) in patient's shoe. Pulse train is programmed by clinician for fixed duration or terminated after footswitch contact. |

Substantial equivalence data – basic characteristics.

| | **ODFS® Pace XL Modified device** | **ODFS® Pace Marketed device** | **ODFS III v6.2 Marketed device** |
|---|---|---|---|
| 510(k) number | Not cleared | K102115 | K050991 |
| Device Name | ODFS® Pace XL dropped foot stimulator | ODFS® Pace dropped foot stimulator | ODFS Dropped foot stimulator (ODFS III V6.2) |
| Manufacturer | Odstock Medical Ltd | Odstock Medical Ltd | Odstock Medical Ltd |
| Power sources | 9V Alkaline battery (ANSI 1604A)<br>9V LiPo rechargeable (same physical form – removed for charging) | 9V Alkaline battery (ANSI 1604A) | 9V Alkaline battery (ANSI 1604A) |
| Method of line current isolation | No mains power connection. Internal 9V battery only | No mains power connection. Internal 9V battery only | No mains power connection. Internal 9V battery only |
| Patient leakage current | Normal condition: <10µA<br>Single fault condition: <25µA | Normal condition: <10µA<br>Single fault condition: <25µA | Normal condition: <10µA<br>Single fault condition: <100µA |
| No. of output modes | 2, Symmetrical and Balanced Asymmetrical | 2, Symmetrical and Balanced Asymmetrical | 2, Symmetrical and Balanced Asymmetrical |
| Number of output channels | 1 | 1 | 1 |
| Synchronous or alternating? | Not applicable – single channel device | Not applicable – single channel device | Not applicable – single channel device |
| Channel isolation method | Not applicable – single channel device | Not applicable – single channel device | Not applicable – single channel device |
| Regulated current or regulated voltage? | Regulated voltage, source resistance effectively = 360Ω | Regulated voltage, source resistance effectively = 360Ω | Regulated voltage, source resistance effectively = 360Ω |
| Software/ Firmware/ Microprocessor control? | Yes | Yes | No |
| Automatic overload trip | No | No | No |
| Automatic No-Load trip | No | No | No |
| Automatic shut off | Yes(after 4hr in 'sleep' state) | Yes (after 4hr in 'sleep' state) | No |
| Patient override control | Yes (Pause button) | Yes (Pause button) | Yes (Pause button) |
| Indicator display | | | |
| On/Off status | Yes – LCD displays function | Yes – LCD displays function | No, audio at on/off, pause/un-pause. Stim On indicator light |
| Low battery | Yes – via LCD | Yes – via LCD | Yes |
| Voltage/current level | Yes – via LCD | Yes – via LCD | Yes, number rotary dial |

| | **ODFS® Pace XL Modified device** | **ODFS® Pace Marketed device** | **ODFS III v6.2 Marketed device** |
|---|---|---|---|
| Timer range (exercise) | 5 to 100 minutes in 5 min steps plus unlimited | 5 to 100 minutes in 5 min steps plus unlimited | Not applicable |
| Compliance with voluntary standards | Yes<br>EN60601-1:2006<br>EN60601-1-2:2007<br>EN60601-2-10:2001 | Yes<br>EN60601-1:2006<br>EN60601-1-2:2007<br>EN60601-2-10:2001 | Yes<br>EN60601-1<br>EN60601-1-2<br>EN60601-2-10 |
| Compliance with 21 CFR 898 | Yes | Yes | Yes |
| Weight | 112g with battery | 112g with battery | 146g with battery |
| Dimensions | 7.2cm x 6.2 cm x 2.6cm | 7.2cm x 6.2 cm x 2.6cm | 6cm (w) x 3cm (h) x 11cm(d) |
| Housing material and construction | Custom moulded ABS plastic enclosure with clear window for LCD | Custom moulded ABS plastic enclosure with clear window for LCD | Moulded thermoplastic case with plastic front panel |
| Accessories | In shoe wired footswitch.<br><br>In shoe wireless footswitch (insole)<br>Or<br>In shoe footswitch with external wireless transmitter (OML Linq™)<br><br>Electrode cable.<br>Self adhesive skin-surface electrodes.<br>[Option] ODFS® Leg cuff for electrode location and device mounting. (also applicable to ODFS® Pace) | In shoe wired footswitch.<br>Electrode cable.<br>Self adhesive skin-surface electrodes. | In shoe wired footswitch.<br>Electrode cable.<br>Self adhesive skin-surface electrodes. |

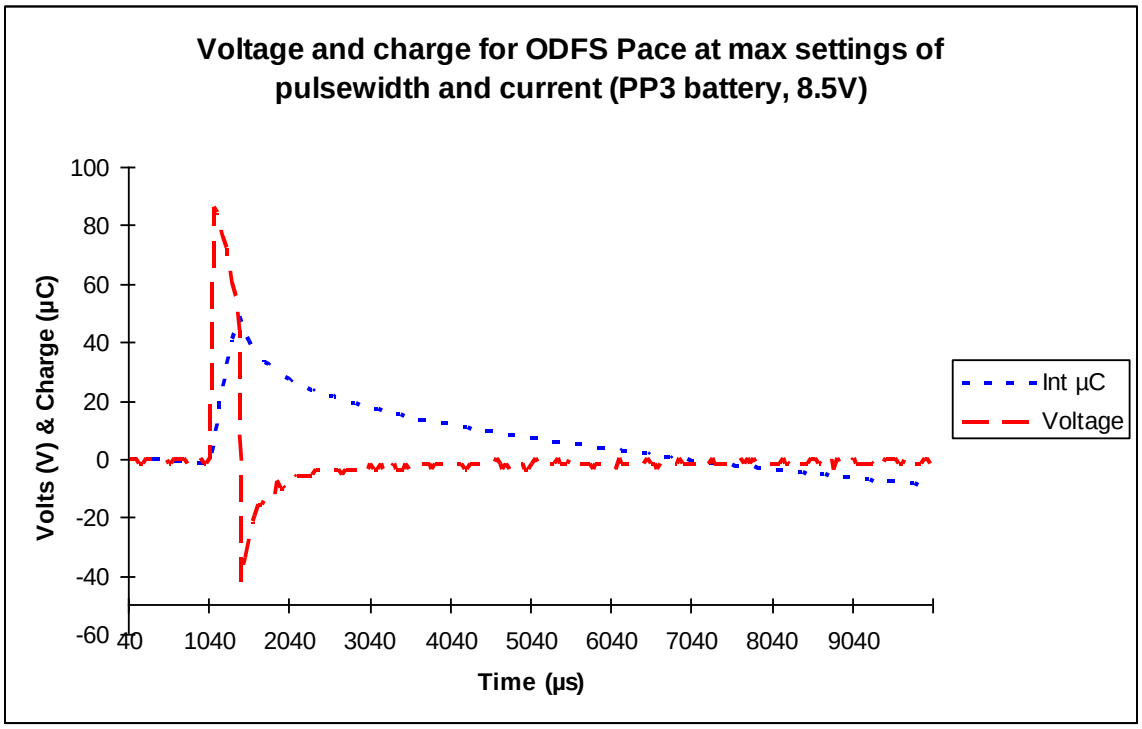
Output calculations:

FDA Guidance suggests measurements to be made at a load resistance of 500R. Measurements made with 10x probe and digital oscilloscope calibrated against reference ‘scope with traceable calibration.

Under these conditions:
R = 500R
Single pulse measurement:

| | |
|---|---|
| peak V | 86V, |
| peak instantaneous current, | 172mA |
| therefore RMS voltage (scope measurement function) | 8.0V to 8.5V |
| (depending on how many pulses incorporated into measurement) | |
| RMS current | 16mA to 17mA |
| Max phase charge (taken as peak forward charge) | 48µCoulombs<br>@ approx 320µs |

(“integrate” by summing V/500 at each 80µs sampling interval in a spreadsheet)




Charge balances at approx 6ms from pulse leading edge.

Current density and power density calculations:

Smallest recommended electrodes: 5cm x 5cm square PALS, area = $25cm^2$

Current density:
peak 172/25 = **$6.9mA.cm^{-2}$**
RMS 17/25 = **$0.68mA.cm^{-2}$**

Power density using $P=V^2/R$:

peak $(86^2/500)/25$ = **$0.6W.cm^{-2}$**
RMS $(8.5^2/500)/25$ = **$5.8mW.cm^{-2}$**

--x--