K972698

510(k) Premarket Notification
Organon Teknika Corporation
TOF-Watch®

510(k) Summary
TOF-Watch®

DEC 16 1997

(a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

Submitter's Name: Organon Teknika Corporation

Submitter's Address: 100 Akzo Avenue, Durham, North Carolina, 27712 USA

Submitter's Telephone: (919) 620-2288

Submitter's Contact: Rebecca A. Rivas Rebecca A. Rivas

Date 510(k) Summary Prepared: July 16, 1997

(a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

Trade or Proprietary Name: TOF-Watch®

Common or Usual Name: TOF-Watch®

Classification Name: Peripheral Nerve Stimulator

(a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

Device Equivalent to: Organon Teknika - TOF-Guard
Neuro Technology - Digistim 3 Plus

(a)(4) **A description of the device.**
Device Description: TOF Watch® device is a neuromuscular transmission monitor capable of estimating the degree of neuromuscular block in anesthetized patients. It can be used as an objective monitor using accelerometry for measuring the muscle contraction following a stimulation of the respective motorneuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring and as a nerve location device utilizing a needle elctrode (needle electrode not supplied by Organon Teknika).

(a)(5) **A statement of the intended use of the device.**

Device Intended Use: TOF Watch® is a device which can be used for monitoring neuromuscular transmission by means of acceleromyography, for peripheral nerve stimulation, and also as a nerve locator for loco-regional anesthesia.

(a)(6) **A summary of the technological characteristics of the new device in comparison to those of the predicate device.**

Feature	TOF-Watch®	TOF-Guard[INMT]	DigiSTIM 3 PLUS
Intended Use	1.Objective neuromuscular transmission monitoring 2.Subjective neuromuscular transmission monitoring 3.Nerve location for loco-regional anesthesia	Objective neuromuscular transmission monitoring	1. Subjective neuromuscular transmission monitoring. 2. Nerve location for loco-regional anesthesia
Output	For 1 and 2: Constant current,0-60 mA, monophasic 200 µsec pulse width, max voltage 300 V (60 mA into 5000 ohm) For 3: Constant current, 0-6mA, monophasic,40 µsec pulse width, max voltage 6V (6mA into 1000 ohm)	Constant current, 0-60 mA monophasic, 200 or 300 µsec pulse width, max voltage 300 V(60 mA into 5000 ohm)	For 1: Constant current, 0-70 mA, monophasic, 200 µsec pulse width max voltage 140 V (70 mA into 2000 ohm) For 2: Constant current, 0-6mA, monophasic, 200 µsec pulse width, max voltage 12 V (6mA into 2000 ohm)
Stimula-tion	TOF (Train of Four) PTC (Post Tetanic Count) 1 Hz Twitch 0.1 Hz Twitch Tetanic stimulation (50 or100 Hz) DBS 3.3 and 3.2 (Double Burst) Auto (calibration of acceleration transducer at set current)	TOF (Train of Four) PTC (Post Tetanic Count) 1 Hz Twitch 0.1 Hz Twitch SLOW TOF DBS 3.3 and 3.2 (Double Burst) AutoI(Calibration of acceleration transducer at supramaximal current AutoII(Calibration of acceleration transducer at submaximal current)	TOF (Train of Four) PTC (Post Tetanic Count) 1 Hz Twitch 2 Hz Twitch Tetanic stimulation (50 or100 Hz) DBS 3.3 (Double Burst)

(b)1) **A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Testing was performed to establish the performance characteristics of the new device including: Risk Analysis,Failure Mode and Effect Analysis, Type Test Report, EMC Report and FCC Report.

1. Functionality - analysis of output current at different simulated skin resistances.
2. Internal checking of software
3. Safety testing - performed according to EN60601 series,IEC 601-2-10 and standards set forth in Medical Device Directive (93/42/EEC).

(b)(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.

Not Applicable.

(b)3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).

The performance characteristics of the new device are substantially equivalent to those of the predicate devices and typical of these systems in general. The results of testing for functionality, internal checking of software, and safety testing performed in accordance with EN60601 series, IEC 601-2-10 and standards set forth in Medical Device Directive (93/42/ECC) demonstrate that the device is safe and effective and meets the requirements of safety for these types of devices..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

DEC 16 1997

Ms. Rebecca A. Rivas
Organon Teknika Corporation
100 Akzo Avenue
Durham, North Caralina 27712

Re: K972698
TOF-Watch
Regulatory Class: II (two)
Product Code: 73 KOI
Dated: December 2, 1997
Received: December 3, 1997

Dear Ms. Rivas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your dev`ice to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K972698

510(k) Premarket Notification
Organon Teknika Corporation
TOF-Watch®

510(k) Summary
TOF-Watch®

DEC 16 1997

(a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

Submitter's Name: Organon Teknika Corporation

Submitter's Address: 100 Akzo Avenue, Durham, North Carolina, 27712 USA

Submitter's Telephone: (919) 620-2288

Submitter's Contact: Rebecca A. Rivas Rebecca A. Rivas

Date 510(k) Summary Prepared: July 16, 1997

(a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

Trade or Proprietary Name: TOF-Watch®

Common or Usual Name: TOF-Watch®

Classification Name: Peripheral Nerve Stimulator

(a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

Device Equivalent to: Organon Teknika - TOF-Guard
Neuro Technology - Digistim 3 Plus

(a)(4) **A description of the device.**
Device Description: TOF Watch® device is a neuromuscular transmission monitor capable of estimating the degree of neuromuscular block in anesthetized patients. It can be used as an objective monitor using accelerometry for measuring the muscle contraction following a stimulation of the respective motorneuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring and as a nerve location device utilizing a needle elctrode (needle electrode not supplied by Organon Teknika).

(a)(5) **A statement of the intended use of the device.**

Device Intended Use: TOF Watch® is a device which can be used for monitoring neuromuscular transmission by means of acceleromyography, for peripheral nerve stimulation, and also as a nerve locator for loco-regional anesthesia.

(a)(6) **A summary of the technological characteristics of the new device in comparison to those of the predicate device.**

Feature	TOF-Watch®	TOF-Guard[INMT]	DigiSTIM 3 PLUS
Intended Use	1.Objective neuromuscular transmission monitoring 2.Subjective neuromuscular transmission monitoring 3.Nerve location for loco-regional anesthesia	Objective neuromuscular transmission monitoring	1. Subjective neuromuscular transmission monitoring. 2. Nerve location for loco-regional anesthesia
Output	For 1 and 2: Constant current,0-60 mA, monophasic 200 µsec pulse width, max voltage 300 V (60 mA into 5000 ohm) For 3: Constant current, 0-6mA, monophasic,40 µsec pulse width, max voltage 6V (6mA into 1000 ohm)	Constant current, 0-60 mA monophasic, 200 or 300 µsec pulse width, max voltage 300 V(60 mA into 5000 ohm)	For 1: Constant current, 0-70 mA, monophasic, 200 µsec pulse width max voltage 140 V (70 mA into 2000 ohm) For 2: Constant current, 0-6mA, monophasic, 200 µsec pulse width, max voltage 12 V (6mA into 2000 ohm)
Stimula-tion	TOF (Train of Four) PTC (Post Tetanic Count) 1 Hz Twitch 0.1 Hz Twitch Tetanic stimulation (50 or100 Hz) DBS 3.3 and 3.2 (Double Burst) Auto (calibration of acceleration transducer at set current)	TOF (Train of Four) PTC (Post Tetanic Count) 1 Hz Twitch 0.1 Hz Twitch SLOW TOF DBS 3.3 and 3.2 (Double Burst) AutoI(Calibration of acceleration transducer at supramaximal current AutoII(Calibration of acceleration transducer at submaximal current)	TOF (Train of Four) PTC (Post Tetanic Count) 1 Hz Twitch 2 Hz Twitch Tetanic stimulation (50 or100 Hz) DBS 3.3 (Double Burst)

(b)1) **A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Testing was performed to establish the performance characteristics of the new device including: Risk Analysis,Failure Mode and Effect Analysis, Type Test Report, EMC Report and FCC Report.

1. Functionality - analysis of output current at different simulated skin resistances.
2. Internal checking of software
3. Safety testing - performed according to EN60601 series,IEC 601-2-10 and standards set forth in Medical Device Directive (93/42/EEC).

(b)(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.

Not Applicable.

(b)3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).

The performance characteristics of the new device are substantially equivalent to those of the predicate devices and typical of these systems in general. The results of testing for functionality, internal checking of software, and safety testing performed in accordance with EN60601 series, IEC 601-2-10 and standards set forth in Medical Device Directive (93/42/ECC) demonstrate that the device is safe and effective and meets the requirements of safety for these types of devices..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

DEC 16 1997

Ms. Rebecca A. Rivas
Organon Teknika Corporation
100 Akzo Avenue
Durham, North Caralina 27712

Re: K972698
TOF-Watch
Regulatory Class: II (two)
Product Code: 73 KOI
Dated: December 2, 1997
Received: December 3, 1997

Dear Ms. Rivas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your dev`ice to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K972698/A1

510(k) Number (if known): K972698

Device Name: TOF-Watch

Indications For Use:

The TOF-Watch device can be used as an objective monitor using accelerometry for measuring the muscle contraction following a stimulation of the respective motorneuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring or as a nerve location device utilizing a needle electrode.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K972698

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

5/59