Avazzia Inc.

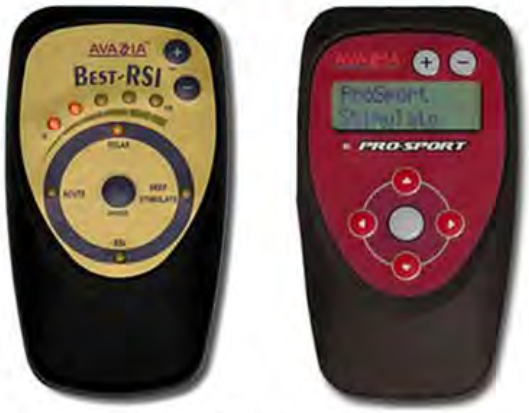
Certification and Device Clearance

List of Clearance Certificates

Device Clearance References from Major Governing Bodies

AVAZZIA

health and wellness techology



AVAZZIA, INC.
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Document Reference: avazzia-cert
Document Version: 001
Document Date: May 3rd 2010

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TABLE OF CONTENTS

510(k) Premarket Notification Database

Device Classification Name	Stimulator, Nerve, Transcutaneous, For Pain Relief
510(K) Number	K062641
Regulation Number	882.5890
Device Name	BODY-STIM, BIOMODULATOR, BEST-RSI, BEST PRO, MODE
Applicant	AVAZZIA, INC. 13154 Coit Rd., Ste. 200 Dallas, TX 75240
Contact	Catherine Tone
Classification Product Code	GZJ
Date Received	09/06/2006
Decision Date	04/30/2007
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Physical Medicine
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 5/08/2007

Medical Devices Active Licence Listing

Overview | What's New (2007-10-10) | Archived Licence Search | Advisories & Warnings | Contact Us

New Search

Revision Date: 2010-04-30

Manufacturer
AVAZZIA, INC.
13154 Coit Road, Suite 200
Dallas, TX, US, 75240

Company ID: 131173

Licence No.: 82319

Type: Device Family

Licence Section		
Device Class	**First Issue Date**	**Licence Name**
2	2010-03-19	LEAD WIRES FOR - TENS AND MUSCLE STIMULATION DEVICES

Device Section		Identifier Section	
First Issue Date	**Device Name**	**First Issue Date**	**Device Identifier**
2010-03-19	LEAD WIRE	2010-03-19	CL-250-15KO
2010-03-19	LEAD WIRE FOR B.E.S.T. TENS DEVICE	2010-03-19	CL-130-RB
		2010-03-19	CL-250-250
		2010-03-19	CL-250-RB
2010-03-19	SPLITTER LEAD WIRE	2010-03-19	CL-SPLITTER

Licence No.: 82320

Type: Device Family

Licence Section		
Device Class	**First Issue Date**	**Licence Name**
2	2010-03-19	CUTANEOUS ELECTRODES FOR TENS OR MUSCLE STIMULATION

Medical Devices Active Licence Listing

Device Section		Identifier Section	
First Issue Date	Device Name	First Issue Date	Device Identifier
2010-03-19	ANKLE ELECTRODES	2010-03-19	J-A
2010-03-19	ARM/LEG WRAP ELECTRODES	2010-03-19	J-AL
2010-03-19	BACK WRAP ELECTRODES	2010-03-19	J-BW
2010-03-19	CERVICAL ELECTRODES	2010-03-19	J-CN
2010-03-19	COMB ELECTRODE	2010-03-19	ELEC-COMB
2010-03-19	CONDUCTIVE ARM SLEEVE ELECTRODE	2010-03-19	W-CAS
2010-03-19	CONDUCTIVE CARPAL TUNNEL ELECTRODE	2010-03-19	W-CTW
2010-03-19	CONDUCTIVE CLIP ELECTRODES	2010-03-19	S-CLIP
2010-03-19	CONDUCTIVE GLOVE ELECTRODE	2010-03-19	W-CG
2010-03-19	CONDUCTIVE LEG SLEEVE ELECTRODE	2010-03-19	W-CLS
2010-03-19	CONDUCTIVE SOCK ELECTRODE	2010-03-19	W-CS
2010-03-19	ELBOW ELECTRODES	2010-03-19	J-E
2010-03-19	FINGER ELECTRODE	2010-03-19	W-BLUE
2010-03-19	KNEE WRAP ELECTRODES	2010-03-19	J-K
2010-03-19	PENCIL ELECTRODE	2010-03-19	ELEC-PEN
2010-03-19	SELF-ADHESIVE ELECTRODE PADS	2010-03-19	W-2020
		2010-03-19	W-3050
2010-03-19	SHOULDER ELECTRODES	2010-03-19	J-S
2010-03-19	Y-ELECTRODE	2010-03-19	ELEC-Y

Licence No.: 82321 **Type: Device Family**

Licence Section		
Device Class	First Issue Date	Licence Name
2	2010-03-19	COMBINATION DEVICES - TENS AND MUSCLE STIMULATION

Medical Devices Active Licence Listing

Device Section		Identifier Section	
First Issue Date	Device Name	First Issue Date	Device Identifier
2010-03-19	AVAZZIA BLUE DEVICE	2010-03-19	A-AB
2010-03-19	BEST-PRO BIOFEEDBACK DEVICE	2010-03-19	A-BP
2010-03-19	BEST-RSI DEVICE	2010-03-19	A-RS
2010-03-19	BODY-STIM DEVICE	2010-03-19	A-BS
2010-03-19	MED-BEST	2010-03-19	A-MED-BEST
2010-03-19	MED-SPORT DEVICE	2010-03-19	A-MED-SPORT
2010-03-19	PRO-SPORT BIOFEEDBACK DEVICE	2010-03-19	A-PS

New Search

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and Nemko AS
hereby certify that the organization

Avazzia Inc
13154 Coit Rd. Suite 200
Dallas, TX 75240 USA

for the following field of activities

Design, manufacture, and distribution of therapeutic devices

has implemented and maintains a

Management System

which fulfils the requirements of the following standard

ISO 13485:2003

Issued on: 2007-03-01
Validity date: 2010-03-01

Registration Number : NO-908068

René Wasmer
President of IQNet

Pål Eddie
Nemko AS
Certification Dept.

IQNet Partners*:
AENOR *Spain* AFAQ AFNOR *France* AIB-Vinçotte International *Belgium* ANCE *Mexico* APCER *Portugal* CISQ *Italy* CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS *Germany* DS *Denmark* ELOT *Greece* FCAV *Brazil* FONDONORMA *Venezuela* HKQAA *Hong Kong China* ICONTEC *Colombia* IMNC *Mexico* Inspecta Certification *Finland* IRAM *Argentina* JQA *Japan* KFQ *Korea* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland* QMI *Canada* Quality Austria *Austria* RR *Russia* SAI Global *Australia* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* YUQS *Serbia*
IQNet is represented in the USA by: AFAQ AFNOR, AIB-Vinçotte International, CISQ, DQS, NSAI Inc., QMI and SAI Global
* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Ref. Certif. No.

NO41831

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

Product Produit	Transcutaneous Electrical Nerve Stimulation Device
Name and address of the applicant Nom et adresse du demandeur	Avazzia Inc. 13154 Coit Road, Suite 200 Dallas, TX 75240 USA
Name and address of the manufacturer Nom et adresse du fabricant	Avazzia Inc. 13154 Coit Road, Suite 200 Dallas, TX 75240 USA
Name and address of the factory Nom et adresse de l'usine *Note: When more than one factory, please report on page 2* *Note: Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*	Avazzia Inc. 13154 Coit Road, Suite 200 Dallas, TX 75240 USA ☐ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	Internally Powered: 3.0V (2 x AA cells) or one 9.0V battery Type BF applied part
Trademark (if any) Marque de fabrique (si elle existe)	AVAZZIA
Model / Type Ref. Ref. De type	BEST-AV1
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page	☐ Additional Information on page 2
	PUBLICATION
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1:1988 + A1:1991 + A2:1995 EMC: IEC 60601-1-2 (ed.2)
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	78456

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

Nemko

P.O. BOX 73, BLINDERN
N-0314 OSLO, NORWAY

Hanne Yndestad

Date: 2006-12-19

Signature: Hanne Yndestad
Certification Department

CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU0702404
Order No.: 70398

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 12th January 1995 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer:	Avazzia, Inc. 13154 Coit Road, Suite 200 Dallas, TX 75240 USA
Device category:	Transcutaneous electrical nerve stimulation
GMDN Code:	See Appendix 1 to this certificate
Models:	See Appendix 1 to this certificate
Risk class as defined by the manufacturer:	IIa
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4
Date of audit:	2006-12-20
Date of the end of the validity:	2012-03-01
Nemko EC notification No.:	0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2007-02-28

Arild Hansgård

Signature: Arild R. Hansgård
Principal Engineer

Date of verification: 2007-02-28

Frank Skarpsno

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

CE 0470

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N-0314 Oslo, Norway

Office address
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Oslo

Telephone
+47 22 96 03 30
Enterprise number:

Fax
+47 22 960 550
NO 9443522430

CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU0702404
Order No.: 70398

Manufacturer: Avazzia, Inc.
13154 Coit Road, Suite 200
Dallas, TX 75240
USA

Device category: Transcutaneous electrical nerve stimulation

Appendix 1: Page 1 of 1

The certificate referred to above includes the following devices:

Devices / GMDN Codes:	*Models*
-	
Transcutaneous electrical nerve stimulation cables/Lead GMDN code: 16315	Body Stim BEST-RSI BEST-Pro1 Biomodulator Med-BEST Med-Sport eZZi-Lift Ezzi-Toner Avazzia Blue BEST-Vet Best-Vet-Pro
TENS electrode, (transcutaneous electrical nerve stimulation) GMDN code: 17191	Combo Probe (accessory) Face Probe (accessory) Pencil Probe (accessory) Y Probes (accessories)
Electrode lead wire GMDN code: 16312	Lead wires

Date of issue: 2007-01-12
Arild Hansgård
Signature: Arild R. Hansgård

Date of verification: 2007-01-12
Frank Skarpsno
Signature: Frank Skarpsno

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