Records processed under FOIA Request 2014-1543; Released 11/12/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Adept Medical LTD.
c/o Mr. Jason Marsh
2 McDonald Street, Morningside
Auckland, New Zealand 1003

Re: K061058
Trade/Device Name: Neozoline Ventilation Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulation Class: II
Product Code: ETD
Dated: June 16, 2006
Received: June 19, 2006

Dear Mr. Marsh:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known): K061058

Device Name: Neozoline Ventilation Tubes

Indications For Use:

The largest patient population are children between 4 months and 6 years of age (but not exclusively). Otological ventilation tubes are indicated for patients with:

- Chronic or recurrent otitis media with persistent effusion (OME).
- Recurrent acute otitis media.
- Acute otitis media with complications.
- Eustachian tube dysfunction resulting in one or more of the following: significant and symptomatic hearing loss, otalgia, vertigo, and tinnitus.
- Hearing loss resulting from bilateral chronic middle ear effusion.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND/OR~~ Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(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 Ophthalmic Ear, Nose and Throat Devises

510(k) Number K061058

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2006

Adept Medical
c/o Jason Marsh
P.O. Box 10075
Dominion Road
Auckland, New Zealand

Re: K061058
Trade/Device Name: Neozoline Ventilation Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tubes
Regulatory Class: Class II
Product Code: ETD
Dated: June 16, 2006
Received June 19, 2006

Dear Mr. Marsh:

This letter corrects our substantially equivalent letter of July 12, 2006.

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 (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.

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Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

K061058

Stuart, Julie (Brandi)

From: Shulman, Marjorie G.
Sent: Tuesday, August 22, 2006 3:00 PM
To: Baker, Karen
Cc: Garcia, Diane; Stuart, Julie (Brandi)
Subject: RE: 510 (k) APPROVAL--LISTING & REGISTRATION

Hi Karen,

(b)(4) Trade Secret Process

[redacted]

Marjie

Marjorie Shulman
Premarket Notification (510(k)) Staff
(301) 594-1190 x 132
email: marjorie.shulman@fda.hhs.gov (please note new email address)

****
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

Protecting and Promoting Public Health

From: Baker, Karen
Sent: Tuesday, August 22, 2006 7:57 AM
To: Shulman, Marjorie G.
Subject: FW: 510 (k) APPROVAL--LISTING & REGISTRATION

(b)(4) Trade Secret Process

[redacted]

3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Karen

From: Jason Marsh [mailto:jmarsh@adept.co.nz]
Sent: Thursday, August 17, 2006 5:44 PM
To: Baker, Karen
Subject: RE: 510 (k) APPROVAL--LISTING & REGISTRATION

(b)(4) Trade Secret Process

[redacted]

Jason

From: Baker, Karen [mailto:karen.baker@fda.hhs.gov]
Sent: Thursday, 17 August 2006 11:59 p.m.
To: Jason Marsh
Subject: RE: 510 (k) APPROVAL--LISTING & REGISTRATION

(b)(4) Trade Secret Process

[redacted]

Karen

From: Jason Marsh [mailto:jmarsh@adept.co.nz]
Sent: Wednesday, August 16, 2006 8:54 PM
To: Baker, Karen
Subject: FW: 510 (k) APPROVAL--LISTING & REGISTRATION

Hello Karen,

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

(b)(4) Trade Secret Process

[redacted]

Regards,

Jason Marsh

Quality Systems Manager

Adept Medical Limited

Auckland, New Zealand.

From: Anthony Blyth
Sent: Thursday, 17 August 2006 8:45 a.m.
To: Jason Marsh
Cc: Murray Fenton
Subject: FW: 510 (k) APPROVAL--LISTING & REGISTRATION

Jason

(b)(4) Trade Secret Process

[redacted]

Anthony Blyth

Adept Medical Limited **www.adeptmedical.co.nz**

Tel: +64 9 815 5285 Fax: +64 9 846 6976

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

From: Craig Parks [mailto:CraigP@jedmed.com]
Sent: Thursday, 17 August 2006 2:57 a.m.
To: Anthony Blyth
Subject: 510 (k) APPROVAL--LISTING & REGISTRATION

ANTHONY,

(b)(4) Trade Secret Process

[redacted]

Sincerely,

Craig Parks

Regulatory Affairs / Q.A.

JEDMED INSTRUMENT COMPANY

Phone: 314-845-3770

Fax: 314-845-3771

Email: CRAIGP@JEDMED.COM

Website: JEDMED.COM

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computer.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Adept Medical LTD.
c/o Mr. Jason Marsh
2 McDonald Street, Morningside
Auckland, New Zealand 1003

Re: K061058
Trade/Device Name: Neozoline Ventilation Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulation Class: II
Product Code: ETD
Dated: June 16, 2006
Received: June 19, 2006

Dear Mr. Marsh:

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.

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Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known): K061058

Device Name: Neozoline Ventilation Tubes

Indications For Use:

The largest patient population are children between 4 months and 6 years of age (but not exclusively). Otological ventilation tubes are indicated for patients with:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND/OR~~ Over-The-Counter Use ___ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K061058

3

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DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Penalty for Private Use $300

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Adept Medical LTD.
c/o Mr. Jason Marsh
2 McDonald Street, Morningside
Auckland, New Zealand 1003

Re: K061058
Trade/Device Name: Neozoline Ventilation Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulation Class: II
Product Code: ETD
Dated: June 16, 2006
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Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use

510(k) Number (if known): K061058

Device Name: Neozoline Ventilation Tubes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K061058

3

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 12, 2006

ADEPT MEDICAL LTD
2 MCDONALD STREET, MORNINGSIDE
AUCKLAND,
NEW ZEALAND 1003
ATTN: JASON MARSH

510(k) Number: K061058
Product: NEOZOLINE VENTILATION TUBES

(b)(4) Trade Secret Process

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

(b)(4) Trade Secret Process

[redacted]

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 19, 2006

ADEPT MEDICAL LTD
2 MCDONALD STREET, MORNINGSIDE
AUCKLAND,
NEW ZEALAND 1003
ATTN: JASON MARSH

510(k) Number: K061058
Received: 17-APR-2006
Product: NEOZOLINE
VENTILATION TUBES

(b)(4) Trade Secret Process

[redacted]

116

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

(b)(4) Trade Secret Process

[redacted]

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
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K061058

Form Approved. OMB No. 0910-511 Expiration Date: August 31, 2005 See Instructions for OMB Statement

EPARTMENT OF HEALTH AND HUMAN SERVICES
. OOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: [redacted] (b
Write the Payment Identification number on your check. b

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ADEPT MEDICAL LIMITED
2 McDonald Street Morningside
Auckland AK 1003
NZ

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
NO DATA

2. CONTACT NAME
Jason Marsh

2.1 E-MAIL ADDRESS
jmarsh@adept.co.nz

2.2 TELEPHONE NUMBER (include Area code)
6498152997

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
NO DATA

. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4) [redacted]
11-Apr-2006

Form FDA 8601 (08/2003)

SK6
FN
II
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/04/2006	MD6025406-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
Amendment	Amendment	☐ Additional Information	☐ Additional Information	☐ Other
Supplement	Supplement			*(describe submission)*:
	Report			
	Report Amendment			

Have you used or cited Standards in your submission? ☑ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Adept Medical Ltd	Establishment Registration Number *(if known)*:		
Division Name *(if applicable)*:	Phone Number *(including area code)*: (09) 8152999		
Street Address: 2 McDonald Street, Morningside	FAX Number *(including area code)*: (09) 8466976		
City: Auckland	State / Province:	ZIP/Postal Code: 1003	Country: New Zealand
Contact Name: Jason Marsh			
Contact Title: Quality System Manager	Contact E-mail Address: jmarsh@adept.co.nz		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )		
Street Address:	FAX Number *(including area code)*: ( )		
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Media Arts (301) 443-1090 EF

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

☐ Process change:
- Manufacturing
- Sterilization
- Packaging
- Other *(specify below)*

☐ Response to FDA correspondence:

☐ Change in design, component, or specification:
- Software / Hardware
- Color Additive
- Material
- Specifications
- Other *(specify below)*

☐ Labeling change:
- Indications
- Instructions
- Performance
- Shelf Life
- Trade Name
- Other *(specify below)*

☐ Location change:
- Manufacturer
- Sterilizer
- Packager

☐ Report Submission:
- Annual or Periodic
- Post-approval Study
- Adverse Reaction
- Device Defect
- Amendment

☐ Change in Ownership
☐ Change in Correspondent
☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

☐ Change in:
- Correspondent / Applicant
- Design / Device
- Informed Consent
- Manufacturer
- Manufacturing Process
- Protocol - Feasibility
- Protocol - Other
- Sponsor

☐ Report submission:
- Current Investigator
- Annual Progress Report
- Site Waiver Report
- Final

☐ Repose to FDA Letter Concerning:
- Conditional Approval
- Deemed Approved
- Deficient Final Report
- Deficient Progress Report
- Deficient Investigator Report
- Disapproval
- Request Extension of Time to Respond to FDA
- Request Meeting
- Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

☑ New Device

☐ Additional or Expanded Indications

☐ Change in Technology

☐ Other Reason *(specify)*:

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SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	ETD	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [x] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Tube, Tympanostomy

	Trade or Proprietary or Model Name for This Device		Model Number
1	Neozoline Ventilation Tubes	1	NZ3211, NZ3212, NZ3111, NZ3112
2		2	NZ3213, NZ3214, NZ3219, NZ3220
3		3	NZ3223, NZ3224, NZ3226, NZ3227
4		4	NZ3121, NZ3122, NZ3123, NZ3124
5		5	NZ3141, NZ3151

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
ETD	874.3880	[ ] Class I [x] Class II
Classification Panel: Ear Nose & Throat		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

Chronic or recurrent otitis media with persistent effusion (OME).
Recurrent acute otitis media.
Acute otitis media with complications.
Eustachian tube dysfunction resulting in one or more of the following: significant and symptomatic hearing loss, otalgia, vertigo, and tinnitus.
Hearing loss resulting from bilateral chronic middle ear effusion.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☑ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Adept Medical Limited		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: (09) 8152999	
Street Address: 2 McDonald Street, Morningside		FAX Number *(including area code)*: (09) 8466976	
City: Auckland		State / Province	ZIP/Postal Code: 1003 / Country: New Zealand
Contact Name: Jason Marsh	Contact Title: Quality System Manager	Contact E-mail Address: jmarsh@adept.co.nz	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )	
Street Address		FAX Number *(including area code)*: ( )	
City: Auckland		State / Province	ZIP/Postal Code: 1003 / Country: New Zealand
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )	
Street Address		FAX Number *(including area code)*: ( )	
City		State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	13485	ISO	Quality systems - Requirements for regulatory purposes	1996	
2	11135	ISO	Validation & Control of EtO Sterilisation testing. Part 1	1994	
3	10993-1	ISO	Biological Evaluation of Medical Devices - Part 1	2003	
4	10993-7	ISO	Biological Evaluation of Medical Devices - Part 7	1995	
5	11138-2	ISO	Sterilisation of Healthcare products - Biological Indicators	1994	
6	14971	ISO	Aplication of Risk Management to Medical Devices	2003	
7	11067	ISO	Packaging for Terminally Sterilised Medical Devices	2005	

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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510(K) Submission, NeoZoline Ventilation Tubes

Adept Medical Limited

Contents

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 **Device Identification**:

Proprietary Device Name: Neozoline Ventilation Tube
Common Device Name: Otological Ventilation Tubes (also known as Tympanostomy Tubes, Ventilation Tubes, Grommets, and Ear Tubes)

2 **Administrative Information**:

Distributor Registration Number: 1926681

JedMed Instrument Co
5416 Jedmed Court
St. Louis, MO 63129-2221

Foreign Manufacturer Registration: Not registered at this time
Establishment registration and Listing will be sent in at same time that the 510(K) submission is sent.

Adept Medical Limited
2 McDonald Street
Morningside
Auckland
New Zealand.
Phone 0064 9 8152999
Fax 0064 9 8466976
Email info@adeptmedical.co.nz

3 **Classification**:

Classification Name: Tube, Tympanostomy
Classification Panel: Ear, Nose and Throat.
Classification Nomenclature: ETD
Class Device II
Regulation Number: 874.3880

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 **510(K) Statement**:

(As required by 21 CFR 807.93)

I certify that in my capacity as an official correspondent/Quality Systems Manager of Adept Medical Limited, I will make available all information included in the premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent.

The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patent identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

_____
Signature of Certifier

_____
Typed Name

_____
Date

_____
Premarket Notification 510 (K) Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 **Truthful & Accurate Statement**:

(As required by 21 CFR 807.87 [K])

I certify that in my capacity as Quality Systems Manager of Adept Medical Limited, I believe to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material has been omitted.

Signature of Certifier

Typed Name

Date

Premarket Notification 510 (K) Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 **Quality System**:

NeoZoline™ products are manufactured under a quality system certified as complying with ISO 13485:1996. The Top level Quality Manual provides a cross reference of regulatory requirements relating to specific markets. These include:

- Title 21, Part 820, Quality System Regulation and associated parts.
- European Union Medical Device Directive (MDD), 12 July 1993, 93/42/EEC
- Canadian Medical Devices Regulations PC 1998-783, 7 May, 1998
- Australian Therapeutic Goods (Medical Devices) Regulations 2002

Refer to Appendix 8 for copies of Certificates.

7 **Technical Standards**:

The following standards apply to the NeoZoline™ Otological Ventilation Tubes:

BS EN	1041	1998	Information supplied by the manufacturer with medical devices
ISO	11135	1994	Medical devices – Validation and routine control of ethylene oxide sterilisation testing – Part 1: General requirements and test methods
ISO	10993-1	2003	Biological evaluation of medical devices – Part 1: Evaluation and testing
ISO	10993-7	1995	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilisation residuals
ISO	11138-2	1994	Sterilisation of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilisation
ISO	14971	2003	Medical devices - Application of risk management to medical devices
ISO	11067	2005	Packaging for terminally sterilized medical devices

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8 **Substantial Equivalence**:

8.1 **Intended Use**:

An otological ventilation tube is a device that is intended to be implanted for ventilation and/or drainage of the middle ear.

An otological ventilations tube is placed in an incision (Myringotomy) usually made in the anterior-superior quadrant of the tympanic membrane. The primary purpose of the device is to ventilate the middle ear, allowing air to enter and thus facilitate the drainage of fluids through the Eustachian tube into the pharynx. A secondary purpose is to provide an alternate route for the exit of middle ear fluid. The principal benefit of myringotomy with insertion of tympanostomy tubes is to keep the middle ear clear of effusion. Other benefits are the restoration of hearing and the aeration of the middle ear to prevent or reverse atelectasis of the tympanic membrane. Removal of middle ear effusion permits normal transmission of sound across the middle ear to the inner ear.

8.2 **Device Description**:

NeoZoline™ Otological Ventilation Tubes (also known as Tympanostomy Tubes, Ventilation Tubes, Grommets, and Ear Tubes). NeoZoline™ Otological Ventilation Tubes include a number of different models which differ in design, material and size. The models include the following designs:

- Collar Button	NZ3211, NZ3212, NZ3111, NZ3112
- Shepard	NZ3213, NZ3214
- Sheehy Collar	NZ3219
- Reuter	NZ3220
- Shah	NZ3223, NZ3224, NZ3226, NZ3227
- Armstrong	NZ3121, NZ3122, NZ3123, NZ3124
- Bevel Bobbin	NZ3141
- Straight Tube	NZ3151

Variants
As well as including different designs, some of the NeoZoline™ Otological Ventilation Tubes feature a "Tail" which is used to assist with removal of the tube.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.3 **Materials**:

(b)(4) Trade Secret Process

[redacted]

8.4 **Schematics & Diagrams**:

For Product Drawings refer to Appendix 2

8.5 **Sterility Information**:

(b)(4) Trade Secret Process

[redacted]

8.6 **Clinical Evaluation**:

(b)(4) Trade Secret Process

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.7 **Biocompatibility Information**:

(b)(4) Trade Secret Process

[redacted]

8.8 **Labelling**:

8.8.1 **Indications for Use**:

The largest patient population are children between 4 months and 6 years of age (but not exclusively). Otological ventilation tubes are indicated for patients with:

- Chronic or recurrent otitis media with persistent effusion (OME).
- Recurrent acute otitis media.
- Acute otitis media with complications.
- Eustachian tube dysfunction resulting in one or more of the following: significant and symptomatic hearing loss, otalgia, vertigo, and tinnitus.
- Hearing loss resulting from bilateral chronic middle ear effusion.

8.8.2 **Contraindications**:

(b)(4) Trade Secret Process

[redacted]

8.8.3 **Possible Adverse Effects To Ventilation Tubes**:

- Early extrusion or expulsion of the ventilation tube.
- Airborne or water contaminants entering through the ventilation tube may result in further infection.
- Ventilation tube may become clogged or blocked and cease to function.
- Certain ventilation tube materials may cause increase tissue irritation due to increased patient allergy or sensitivity.
- Grafting procedures may be required with permanent and/or consistent perforations of the tympanic membrane.

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8.8.4 **Warnings**:

- Do not re-use ventilation tubes.
- Do not re-sterilise the ventilation tube if the case is opened.
- Do not implant the ventilation tube if the pouch which maintains sterility has been previously opened or damaged.
- After insertion of a ventilation tube, to avoid contamination and infection, fluid should be prevented from entering the ear.
- Post-operative complications – It is often difficult to determine if complications occurring after insertion of otological ventilation tubes are due to the tubes or are due to sequalae of the intrinsic disease. Occasionally otological ventilation tubes may contribute to a number of post-operative complications including; secondary infection accompanied by otorrhea through the tube, permanent perforations, dislocation of the tube into the middle ear cavity, tympanosclerosis, and localised or diffuse membrane atrophy.

For examples of Product Labels refer to Appendix 5
For examples of User Instructions refer to Appendix 6

8.9 **Product Comparison**:

Product Comparison – Ventilation Tubes
Predicate Device Labelling

Refer to Appendix 7.

A. **Appendices**

Appendix 1 Checklist for Tympanostomy Tubes
Appendix 2 Product Drawings
Appendix 3 Material Safety Date Sheets
Appendix 4 Sterilisation
Appendix 5 Labelling Samples
Appendix 6 User Instructions
Appendix 7 Product Comparison
Appendix 8 Certificates
Appendix 9 Clinical Evaluation
Appendix 10 Biological Safety Assessment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 1

510K Checklist for Tympanostomy Tubes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(K) Checklist for Tympanostomy Tubes

510 (K) Number _____

Device Number Various

		Present	Needed
1.	**Administrative information**		
a.	Classification name - Tympanostomy Tube	Yes	
b.	Sponsor/manufacturer name and address	Yes	
c.	Procode/Classification - ETD 77, Class II (§ 874.3880)	Yes	
d.	Establishment registration number, or a statement that it has been requested	Yes	
2.	**Reason for the 510(k) submission (new device or a modification to an existing device)**	Yes	
3.	**Device description**	Yes	
4.	**Intended use of the device**		
a.	Description of the materials used	Yes	
b.	If a coating or colorant is used, a list of the precise formulation(s) and the requirements for the coatings	Yes	
c.	Device dimensions including inner diameter, inter-flange diameter, and inter-flange width	Yes	
d.	Description of any special design or features	Yes	
e.	Diagrams, drawings and/or photographs of the device	Yes	
f.	List of the range of sizes/models proposed for marketing	Yes	
5.	**Proposed labeling, instructions for use, advertisements** (per the "Device Labeling Guidance," Blue Book Memo G91-1)		
a.	Intended use with specific indications, i.e., clinical setting, defined target population, etc.	Yes	
b.	Warnings, contraindications, or limitations (21 CFR §807.87(e)	Yes	
c.	Prescription device statement (21 CFR 801.109)	Yes	
d.	Labeled for disposable/single use only	Yes	
e.	Labeled as sterile with expiration date.	Yes	
f.	Types of coatings	No	No
g.	If antimicrobial agent is used as a coating, a characterization of the microbial and its activity	No	No
h.	Advertisements or promotional literature	Yes	
6.	**Biocompatibility** For all materials used to fabricate the tympanostomy tube provide either:		
a.	Evidence that the same formulations of these materials are used in another, similar legally marketed device (provide the device name, manufacturer, and (if possible) 510(k) number); OR	Yes	
b.	The results of the following biocompatibility tests on the finished device (this is the minimum level of required testing for a device implanted in bone/tissue for more than 30 days):		
	(1) Implantation	No	No
	(2) Cytotoxicity	No	No
	(3) Genotoxicity, and	No	No
	(4) Sensitization	No	No

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		Present	Needed
7.	**Sterility information (if the device is labeled or otherwise represented to be sterile)**		
a.	The method of sterilization	Yes	
b.	The method used to validate the sterilization cycle	Yes	
c.	The sterility assurance level (SAL) achieved by the sterilization cycle	Yes	
d.	The levels of the residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol on the device (for ethylene oxide sterilization)	Yes	
e.	The radiation level (in megarads) used (for radiation sterilization)	Yes	
f.	A description of the packaging material used to ensure the sterility of the device	Yes	
g.	The method used to determine that the device is pyrogen free (if pyrogen free claim will be made)	No	No
8.	**Comparison to legally marketed tympanostomy tubes**		
a.	Name/manufacturer of predicate device	Yes	
b.	510(k) number (if known) of the predicate device (or statement that the predicate is pre-Amendment)	Yes	
c.	Labeling of predicate device	Yes	
d.	Intended use of the predicate device	Yes	
e.	Diagrams/photographs of predicate device	Yes	
f.	A comparison of the similarities/differences between the 510(k) device and the predicate device (in tabular format) including design, physical description, patient-contacting materials, performance, and, if applicable, types of coating, amount/concentration of coating(s), tube coating process, and target population	Yes	
9.	**Modified Devices** (for a device that has undergone a change or modification that could significantly affect safety or effectiveness, or for a device to be marketed for a new or different indication for use).		
a.	Rationale for modification with supporting documentation	No	No
b.	Description of significant changes and modifications affecting safety, effectiveness, or intended use.	No	No
c.	Data to support marketing claims (bench, clinical, functional, in vitro, etc.	No	No
9.	**Truthful and accurate statement** (signed and in accordance with 21 CFR 807.87(j)	**Yes**	
10.	**510(k) Summary or 510(k) Statement** (per 21 CFR 807.92 and 807.93)	**Yes**	
11.	**Indications for use statement**	**Yes**	

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Appendix 2

Product Drawings

(b)(4) Trade Secret Process

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Trade Secret Process -Technical Drawings

(b)(4) Trade Secret Process -Technical Drawings

(b)(4) Trade Secret Process -Technical Drawings

(b)(4) Trade Secret Process -Technical Drawings

(b)(4) Trade Secret Process -Technical Drawings

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(b)(4) Trade Secret Process -Technical Drawings

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Appendix 3

Material Safety Data Sheets

3.1 Tefzel® HT-2185
3.2 A11179 White ZnO Pigment
3.3 Topilene J801

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Material Safety Data Sheet

COPY

TEFZEL HT2181, HT2183, HT2185, HT2190, HT2195

Infosafe no. DU0NO **Issue Date** October 1998 **Status** ISSUED by DUPONT

Not classified as hazardous according to criteria of NOHSC

COMPANY DETAILS

Company Name	DuPont (Australia) Ltd (ABN 59 000 716 469)
Address	168 Walker St North Sydney NSW 2060
Emergency Tel.	(02) 9963 1301
Tel/Fax	Tel: (02) 9923 6111 Fax: (02) 9923 6011
er Information	24 hour Medical Emergency: 1800 674 415

(R) DuPont Registered Trademark

DuPont New Zealand
98 Kerrs Road
Manukau
Auckland
New Zealand
Ph: (09) 268 5500 (24 Hours)
NZ Poisons Information Centre Ph: 0800 764766

IDENTIFICATION

Product Name	TEFZEL HT2181, HT2183, HT2185, HT2190, HT2195
Proper Shipping Name	None Allocated

Other Names	**Name**	**Product Code**
	TEFZEL ETFE FLUOROPOLYMERS TEFZEL 200, 207, 750, TEFZEL HT750, TEFZEL HT2004, HT2055, HT2058, TEFZEL RESIN 200, 207, 750 807J	

UN Number	None Allocated
DG Class	None Allocated
Packing Group	None Allocated
Hazchem Code	None Allocated
Poisons Schedule	Not Scheduled
Product Use	Chemicaly resistant parts and containers. Numerous hi tech engineering applications requiring greater flexibility than Teflon FEP or Teflon PFA.

Physical Data

Melting Point	255-280 C (491-536 F)
ecific Gravity	1.7

Other Properties

Other Information Solubility in Water: Insolubil

Ingredients

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ingredients	Name	CAS	Proportion
	TETRAFLUOROETHYLENE-ETHYLENE COPOLYMER	68258-85-5	100 %

HEALTH HAZARD INFORMATION

Health Effects

Acute - Eye Eye contact may cause mechanical irritation with discomfort and tearing.

First Aid

Swallowed No specific intervention is indicated as compound is not likely to be hazardous by ingestion. Consult a physician if necessary.
Eye contact may cause mechanical irritation with discomfort and tearing. Inhalation of fumes from overheating ETFE may cause eye, nose, throat, and lung irritation. Lung effects may be delayed for several hours. Small amounts of carbonyl fluoride and hydrogen fluoride may be evolved when ETFE is overheated or burned.
Inhalation of low concentrations of HYDROGEN FLUORIDE can initially include symptoms of choking, coughing, and severe eye, nose and throat irritation. Possibly followed after a symptomless period of 1 to 2 days by fever, chills, difficulty in breathing cyanosis, and pulmonary edema. Acute or chronic overexposure to HF can injure the liver and kidneys.
Inhalation, ingestion, or skin or eye contact with CARBONYL FLUORIDE may initially include: skin irritation with discomfort or rash; eye corrosion with corneal or conjunctival ulceration; irritation of the upper respiratory passages; or temporary lung irritation effects with cough, discomfort, difficulty breathing, or shortness of breath. By analogy with phosgene, symptoms may be delayed.
Individuals with preexisting diseases of the lungs may have increased susceptibility to the toxicity of excessive exposures from thermal decomposition products.

Eye In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

Skin The compound is not likely to be hazardous by skin contact, but cleansing the skin after use is advisable. If molten polymer gets on skin, cool rapidly with cold water. Do not attempt to peel polymer from skin. Obtain medical treatment for thermal burn.

Inhaled No specific intervention is indicated as the compound is not likely to be hazardous by inhalation. Consult a physician if necessary. If exposed to fumes from overheating or combustion, move to fresh air. Consult a physician if symptoms persist.

Advice to Doctor

Other Health Hazard Information

PRECAUTIONS FOR USE

Exposure Limits

TEFZEL ETFE FLUOROPOLYMERS:
Worksafe TWA : Particulates 10mg/m3
PEL (OSHA) : Particulates (Not Otherwise Regulated)
15 mg/m3, 8 Hr. TWA, total dust
5 mg/m3, 8 Hr. TWA, respirable dust

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hydrogen Fluoride
Worksafe TWA : 3 ppm, 2.6 mg/m3
PEL (OSHA) : 3 ppm, 8 Hr. TWA, as F
TLV (ACGIH) : 3 ppm, 2.6 mg/m3, Ceiling as F
AEL * (DuPont) : 3 ppm, 15 minute TWA
Carbonyl Fluoride
Worksafe TWA : 2 ppm, 5.4 mg/m3
PEL (OSHA) : None Established
TLV (ACGIH) : 2 ppm, 5.4 mg/m3, 8 Hr. TWA
STEL 5 ppm, 13 mg/m3
AEL * (DuPont) : None Established
* AEL is DuPont's Acceptable Exposure Limit. Where governmentally imposed occupational exposure limits which are lower than the AEL are in effect, such limits shall take precedence.

Eng. Controls VENTILATION Use local exhaust to completely remove vapours and fumes liberated during hot processing from the work area.

Personal Protection

Protective Equip. EYE/FACE PROTECTION
Wear safety glasses. Wear coverall chemical splash goggles and face shield when possibility exists for eye and face contact due to splashing or spraying of molten material.
RESPIRATORS
When temperatures exceed 350 deg C (662 deg F) and ventilation is inadequate to maintain concentrations below exposure limits, use a positive pressure air supplied respirator.
Air purifying respirators may not provide adequate protection.
PROTECTIVE CLOTHING
If there is potential contact with hot/molten material, wear heat resistant clothing and footwear.

Flammability

Fire Hazards Flash Ignition Temperature : 470C (878F)
Method : ASTM D1929
Self Ignition Temperature : 510-515C (950-959F)
Method : ASTM D1929
UL-94 Flammability Rating : V-O
Limiting Oxygen Index : 30
Method : ASTM D6283
Average time of burning (ATB) is less than 5 seconds and average length of burn (ALB) IS 10 MM (0.39 in) by ASTM D635 horizontal burn test.
Hazardous gases/vapors produced in fire are hydrogen fluoride (HF), carbon monoxide, potentially toxic fluorinated compounds.

SAFE HANDLING INFORMATION

Storage and Transport

Storage and Transport Keep containers closed to avoid contamination.
Avoid contamination of cigarettes or tobacco with dust from this material.
Do not use a torch to clean this material from equipment without local exhaust ventilation and respirator.

Proper Shipping Name None Allocated

Spills and Disposal

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Spills & Disposal

WASTE DISPOSAL:
Preferred options for disposal are (1) recycling and (2) landfill.
Incinerate only if incinerator is capable of scrubbing out hydrogen fluoride and other acidic combustion products. Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state/provincial and local regulations.

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.
Spilled material is a slipping hazard.

SPILL CLEAN UP:
Recover undamaged and minimally contaminated material for reuse nd reclamation. Shovel or sweep up.
Contact with incompatibles can cause fire, an explosion.
Decomposition
Small amounts of hydrogen fluoride (HF) may be evolved at about 350 deg C (662 deg F), with larger amounts at higher temperatures.

Fire/Explosion Hazard

Fire/Explos. ard

Extinguishing Media
Water, Foam, Dry Chemical, CO2.
Fire Fighting Instructions
Wear self-contained breathing apparatus. Wear full protective equipment. Hydrogen fluoride fumes emitted during a fire can react with water to form hydrofluoric acid. Wear neoprene gloves when handling refuse from fire.

Hazchem Code None Allocated

OTHER INFORMATION

Environment Protection

Ecotoxicological Information
Aquatic Toxicity
Not toxic.

Other Information MSDS=TFZ004 , Revised:=14-OCT-1994Loaded 05/12/1995

CONTACT POINT

tact

For sales, technical, and all product related enquiries contact Du Pont's North Sydney office on 9923 6111. Outside Sydney metropolitan area 1800 252 997 is a toll free number to North Sydney office to assist communications, ask for the customer service, Technical, or marketing personnel for the product family relative to the enquiry.
Telephone numbers for other offices are:
North Sydney: (02) 9923-6111
Melbourne: (03) 9721-5900
Perth: (08) 9316-7111
The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

End of MSDS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Spills & Disposal

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End of MSDS

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Ciba Specialty Chemicals Limited
New Zealand

BU Masterbatch

Colour Match Technical Data Sheet

Ciba
Value beyond Chemistry
COPY

Code		
A	=	Dry Colour Blend
AB	=	ABS
AS	=	ASA
CB	=	CAB
CP	=	CAP
ES	=	Polyester
EV	=	EVA
FP	=	F-PVC
GP	=	Styrene
HD	=	HDPE
HP	=	HIPS
LD	=	LDPE
LL	=	LLDPE
NY	=	Nylon
PC	=	Polycarb
PG	=	PETG
PM	=	Acrylic PMMA
PO	=	Acetal POM
PP	=	Polypropylene
PT	=	PET
RP	=	R-PVC
SA	=	SAN
TU	=	TPU
UN	=	Universal
XX	=	Miscellaneous
1	=	WHITE
2	=	YELLOW/ORANGE
3	=	RED/PINK
4	=	MAROON/PURPLE
5	=	ADDITIVES
6	=	BLUE
7	=	GREEN
8	=	BROWNS/GOLD
9	=	GREY/SILVER/BLACK

CLIENT: **ADEPT**

Date: 6 April 2004

Colour: WHITE ZnO

Light Fastness: 7-8 (blue wool scale, pigments only)

Heat Stability: 280 °C (pigments only)

Food Contact: YES

- The active ingredients in A11179 are allowed for food contact applications within the EU under Directive 95/3/EEC. A11179 has also been cleared by the FDA for use in polymers, resins or additives intended for food contact applications.

Comments: CONTAINS 88.27 % TiO_2 and 11.72 % ZnO.

CODE: **A11179**

47 - 51 Patiki Road, Avondale
Private Bag 19 997, Avondale Auckland 7

Telephone 09 820 1650
Fax 09 820 1651

The information given in this publication is based on the present state of our knowledge but any conclusion and recommendations are made without liability on our part. Buyers and users should make their own assessment of our product under their own conditions and for their own requirements.

Records processed under FOIA Request 2014-1543; Released 11/12/14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ciba

MATERIAL SAFETY DATA SHEET
MSDS No. : WHITE ZNO
Version No. 1
Date 21 JULY 2004

STATEMENT OF HAZARDOUS NATURE

Classified as according to criteria of WORKSAFE AUSTRALIA
may contain traces of *Crystalline Silica*,
a known lung cancer hazard.

Use with adequate dust control measures.
Use a respirator if exposed to dust !!

Avoid dust formation Dust clouds from finely particulated pigments *MAY* be hazardous

COMPANY DETAILS.

CIBA SPECIALTY CHEMICALS N Z. LIMITED
47-51 Patiki Rd, Avondale
Auckland 7

Private Bag 19-997
Avondale, Auckland 7.

[redacted]

IDENTIFICATION

Product Code (New Zealand)	**A11179**
Product Code (Australia)	None Known
Other Name	WHITE ZnO (Ciba computer code, 470108)
Chemical Type	Mixture of PIGMENTS and dispersants
U N Number	None allocated
Dangerous Goods Class	None allocated
Hazchem Code	None allocated
Poisons Schedule	None allocated
Primary Use	Colouration of plastics

PHYSICAL DESCRIPTION & PROPERTIES

Appearance	WHITE Powder
Melting Point	Not applicable
Specific Gravity	n/a
Flashpoint	Not applicable
Flammability Limits	Not known
Solubility in water	Insoluble

Ingredients

Chemical Entity	CAS No	Amount
CRYSTALINE SILICA	1317-65-3	- Trace
AMORPHOUS FUMED SILICA (SiO2)	112945-52-5	- 2.92%

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ciba

MSDS No.: A11179
Version No:1

HEALTH HAZARD INFORMATION

Health Effects

Acute
Repeated and prolonged exposures **may** cause delayed effects involving the RESPORATORY SYSTEM

Chronic *Potential LUNG CANCER HAZARD.*

FIRST AID

Swallowed	If swallowed, give plenty of water to drink. Induce vomiting. Seek medical attention if discomfort persists
Eye	Wash out immediately with running water for 10 minutes
Skin	Wash off with warm, soapy water.
Inhaled	Remove to fresh air Consult Occupational Physician.

Advice to Doctor :

PRECAUTIONS FOR USE

Exposure Standards : TWA (WorkSafe/ACGIH) = 10 mg/m3 Calcium Carbonate
= 0.2 mg/m3 Crystalline Silica

Engineering Controls:
Ventilation Mechanical exhaust suitable for dust control.
If fumes are generated in customer's process, a fume extraction system should be used

PRECAUTIONS FOR USE . When handling observe the usual precautionary measures for chemicals

Personal Protection

Skin	Wear coveralls and impervious gloves.
Eyes	Wear safety spectacles with side shields.eg AS1337.Type HT.CT or D)
Respiratory System	If adequate ventilation is not available use AS1716 class P1 or P2 particulate filter respirator

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ciba

MSDS No.: A11179
Version No.1

FLAMMABILITY

Product will support combustion, but is not a specific fire hazard

SAFE HANDLING INFORMATION

Storage and Transport

General Keep away from food, drink, and heat. Store in sealed container in a cool dry area away from ignition sources

Spills and Disposals

Personal Protection Refer page 2.

Clean Up Spills/Leaks Sweep up promptly or vacuum clean to avoid dusty conditions
Dispose of all waste according to Local or New Zealand Regulations

Land Fill Conditions

FIRE & EXPLOSION HAZARD

Fire/Explosion Hazard

Extinguishing Medium Water,CO2,dry powder, foam.

Hazardous Decomposition Products.

As in all fires beware of noxious, corrosive and combustible gases which may be generated in fire situations

BREATHING APPARATUS TO BE WORN IN FIRE SITUATIONS

OTHER INFORMATION

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

MSDS No.: A11179
Version No.:1

FURTHER INFORMATION

FOLLOW GOOD WORKING PRACTICE: HANDLE WITH CARE, AVOID INGESTION, INHALATION, EYE OR SKIN CONTACT

SINCE WE CANNOT ANTICIPATE OR CONTROL THE MANY DIFFERENT CONDITIONS UNDER WHICH THIS INFORMATION AND OUR PRODUCT MAY BE USED, EACH USER SHOULD REVIEW THESE RECOMMENDATIONS IN THE SPECIFIC CONTEXT OF THE INTENDED APPLICATION AND CONFIRM THAT THEY ARE APPROPRIATE.

THIS VERSION AUTHORISED BY: Mr. I. Dobson (Laboratory Manager)

CIBA SPECIALTY CHEMICALS N Z. LIMITED

47-51 Patiki Rd, Avondale
Private Bag 19-997
Avondale, Auckland 7

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

HYOSUNG Chemicals

450 Gongdeok-Dong Mapo-gu
Seoul, Korea 121-720
Tel : 82-2-707-7545, Fax : 82-2-707-7[illegible]0

TOPILENE
MATERIAL SAFETY DATA SHEET

SECTION ¥°

¡Ý MANUFACTURER'S NAME : HYOSUNG CORPORATION
¡Ý EMERGENCY TELEPHONE NO.: (02) 707-7541/5
¡Ý ADDRESS: 13th Floor, Gongdeok Building, 450, Gongdeok-Dong, Mapo-Gu, Seoul, Korea
¡Ý CHEMICAL NAME AND SYNONYMS: Polypropylene Homo Polymer
¡Ý CAS NO.: 9003-07-0
¡Ý TRADE NAME AND SYNONYMS : TOPILENE J801
¡Ý CHEMICAL FAMILY : Polyolefin
¡Ý FORMULA : (CH2-CHCH3)m

SECTION ¥± - HAZARDOUS INGREDIENT

PAINTS,PRESERVATIVES,SOLVENTS	%WT	TLV(UNITES)	ALLOYS AND METALLIC CONTAINS	%WT	TLV(UNITES)
PIGMENTS	X	None			
VEHICLE	X	None			
SOLVENTS	X	None			
OTHERS					
HAZARDOUS MIXTURES OF OTHER LIQUIDS, SOLIDS OR GASES				%WT	TLV(UNITES)

SECTION ¥² - PHYSICAL DATA

BOILING POINT(760mmHg)	NA	MELTING POINT(¡É)	> 150
VAPOR PRESSURE(mmHg at ¡É)	NA	SPECIFIC GRAVITY(H2O=1)	0.89-0.91
VAPOR DENSITY (AIR=1)	NA	PERCENT VOLATILE BY VOLUME	Max 0.1
SOLUBILITY IN WATER	Insoluble	EVAPORATION RATE(WATER=1)	
APPEARANCE AND ODOR : Solid pellets and no odor			

SECTION ¥³- FIRE AND EXPLOSION HAZARD DATA

FLASH POINT(¡É)	None	FLAMMABLE LIMITS	LOW	NA
			HIGH	NA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

EXTINGUISHING MEDIA: H2O and Chemicals
SPECIAL FIRE FIGHTING PROCEDURES: None
UNUSUAL FIRE AND EXPLOSION HAZARDS: None

SECTION ¥´ - HEALTH HAZARD DATA

¡Ý THRESHOLD LIMIT VALUE:
¡Ý EFFECTS OF OVEREXPOSURE: None in case of acute and chronic overexposure
¡Ý EMERGENCY AND FIRST AID PROCEDURES:

SECTION ¥µ - REACTIVITY DATA

STABILITY	UNSTABLE		CONDITIONS TO AVOID :
	STABLE	¡Ì	
INCOMPATIBILITY(MATERIALS TO AVOID): None			
HAZARDOUS DECOMPOSITION PRODUCTS: Thermal decomposion products may include C, CO, CO2 , H2O and organic vapors.			
HAZARDOUS POLYMERIZATION	MAY OCCUR		CONDITIONS TO AVOID :
	NOT LIKELY	¡Ì	

SECTION ¥¶ - SPILL OR LEAK PROCEDURES

¡Ý STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:
Normal procedures for cleaning up use some form of vacuum cleaner's device.
Contain and transfer spilled material proper containers.
¡Ý WASTE DISPOSAAL METHOD:
All recovered material should be packaged, labeled, transported and disposed or reclaimed in conformance with applicable laws and regulations and in accordance with good engineering practices. Reclaim where possible.

SECTION ¥·-SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION(SPECIFIC TYPE) : In dusty atmosphere, use approved dust respirator		
VENTILATION	LOCAL EXHAUST	SPECIAL :
	MECHANICAL(GENERAL) :	OTHER :
EYE PROTECTION: Not normally required		
PROTECTIVE GLOVES : Not normally required(wear heat protective gloves if there is potential for contact with heated material)		
OTHER PROTECTIVE EQUIPMENT. Same as above		

SECTION ¥¸ - SPECIAL PRECAUTIONS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

¡Ý PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING : Keep in dry area and avoid breathing dusts if generated.

¡Ý OTHER PRECAUTIONS : Keep containers closed when not in use and during transport.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 4

Sterilisation

Sterilisation Validation Update Report for Neozoline Ventilation Tubes and Internal Nasal Splints – January 2004.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Trade Secret Process -Validation Report

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(b)(4) Trade Secret Process -Validation Report

(b)(4) Trade Secret Process -Validation Report

(b)(4) Trade Secret Process -Validation Report

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Appendix 5

Labelling Samples

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

REF NZ3121 **NeoZoline**

VENT TUBE ARMSTRONG
FLUOROPLASTIC ID 1.14mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3121 **NeoZoline**
VENT TUBE ARMSTRONG
FLUOROPLASTIC ID 1.14mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120
PEEL HERE

REF NZ3122 **NeoZoline**

VENT TUBE ARMSTRONG - TAIL
FLUOROPLASTIC ID 1.14mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3122 **NeoZoline**
VENT TUBE ARMSTRONG TAIL
FLUOROPLASTIC ID 1.14mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120
PEEL HERE

REF NZ3212 **NeoZoline**

COLLAR BUTTON MEDIUM TERM VENT TUBE - TAIL
FLUOROPLASTIC ID 1.10mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3212 **NeoZoline**
COLLAR BUTTON MEDIUM TERM VENT TUBE - TAIL
FLUOROPLASTIC ID 1.10mm QTY: 1
STERILE EO °F LOT 200X-1XXX CE 0120
PEEL HERE

REF NZ3211 **NeoZoline**

COLLAR BUTTON MEDIUM TERM VENT TUBE
FLUOROPLASTIC ID 1.10mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3211 **NeoZoline**
COLLAR BUTTON MEDIUM TERM VENT TUBE
FLUOROPLASTIC ID 1.10mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120
PEEL HERE

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REF NZ3213 **NeoZoline**

SHEPARD SHORT TERM VENT TUBE
FLUOROPLASTIC ID 1.10mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3213 **NeoZoline**
SHEPARD SHORT TERM VENT TUBE
FLUOROPLASTIC ID 1.10mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120
PEEL HERE

REF NZ3213-2 **NeoZoline**

SHEPARD SHORT TERM VENT TUBE
FLUOROPLASTIC ID 1.10mm QTY: 10 x 2

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3213-2 **NeoZoline**
SHEPARD SHORT TERM VENT TUBE
FLUOROPLASTIC ID 1.10mm QTY: 2
STERILE EO LOT 200X-1XXX CE 0120
PEEL HERE

REF NZ3214 **NeoZoline**

SHEPARD SHORT TERM VENT TUBE WITH TAIL
FLUOROPLASTIC ID 1.10mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3214 **NeoZoline**
SHEPARD SHORT TERM VENT TUBE WITH TAIL
FLUOROPLASTIC ID 1.10mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120
PEEL HERE

REF NZ3223 **NeoZoline**

SHAH MINI LONG TERM VENT TUBE
FLUOROPLASTIC ID 0.76mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3223 **NeoZoline**
SHAH MINI LONG TERM VENT TUBE
FLUOROPLASTIC ID 0.76mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120
PEEL HERE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

REF NZ3224 **NeoZoline®**

SHAH LONG TERM VENT TUBE
FLUOROPLASTIC ID 1.14mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3224 **NeoZoline®**
SHAH LONG TERM VENT TUBE
FLUOROPLASTIC ID 1.14mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

REF NZ3226 **NeoZoline®**

SHAH MINI LONG TERM VENT TUBE WITH TAIL
FLUOROPLASTIC ID 0.76mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3226 **NeoZoline®**
SHAH MINI LONG TERM VENT TUBE WITH TAIL
FLUOROPLASTIC ID 0.76mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

REF NZ3227 **NeoZoline®**

SHAH LONG TERM VENT TUBE WITH TAIL
FLUOROPLASTIC ID 1.14mm QTY: 10 x 1

STERILE EO LOT 200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

EC REP Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3227 **NeoZoline®**
SHAH LONG TERM VENT TUBE WITH TAIL
FLUOROPLASTIC ID 1.14mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

REF NZ3111 **NeoZoline**

COLLAR BUTTON VENT TUBE
FLUOROPLASTIC ID 1.27mm QTY: 10 x 1

200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3111 **NeoZoline**
COLLAR BUTTON VENT TUBE
FLUOROPLASTIC ID 1.27mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

REF NZ3112 **NeoZoline**

COLLAR BUTTON VENT TUBE - TAIL
FLUOROPLASTIC ID 1.27mm QTY: 10 x 1

200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3112 **NeoZoline**
COLLAR BUTTON VENT TUBE - TAIL
FLUOROPLASTIC ID 1.27mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

REF NZ3123 **NeoZoline**

MODIFIED ARMSTRONG VENT TUBE
FLUOROPLASTIC ID 1.14mm QTY: 10 x 1

200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3123 **NeoZoline**
MODIFIED ARMSTRONG VENT TUBE
FLUOROPLASTIC ID 1.14mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

REF NZ3124 **NeoZoline**

MODIFIED ARMSTRONG VENT TUBE - TAIL
FLUOROPLASTIC ID 1.14mm QTY: 10 x 1

200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3124 **NeoZoline**
MODIFIED ARMSTRONG VENT TUBE - TAIL
FLUOROPLASTIC ID 1.14mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

REF NZ3141 **NeoZoline**

BEVEL BOBBIN VENT TUBE
FLUOROPLASTIC ID 1.14mm QTY: 10 x 1

200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3141 **NeoZoline**
BEVEL BOBBIN VENT TUBE
FLUOROPLASTIC ID 1.14mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

REF NZ3151 **NeoZoline**

STRAIGHT TUBE VENT TUBE
FLUOROPLASTIC ID 1.14mm QTY: 10 x 1

200X-1XXX

Adept Medical Ltd, 6 McDonald St, Morningside, Auckland
Made in New Zealand.

Martello Technology Ltd
Dukes Mead, The Old School, Egloshayle Road
Wadebridge, Cornwall PL27 6AD, United Kingdom

CE 0120

REF NZ3151 **NeoZoline**
STRAIGHT TUBE VENT TUBE
FLUOROPLASTIC ID 1.14mm QTY: 1
STERILE EO LOT 200X-1XXX CE 0120 PEEL HERE

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Appendix 6

User Instructions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NeoZoline™

USER INSTRUCTIONS

Manufactured by Adept Medical Limited
6 McDonald Street, Morningside, Auckland, New Zealand
Tel +64-9-8152999 Fax +64-9-8466976

OTOLOGICAL VENTILATION TUBES (TYMPANOSTOMY TUBES)

STERILE EO 2

An otological ventilation tube or tympanostomy tube (grommet) is a device that is intended to be implanted into the tympanic membrane for ventilation and/or drainage of the middle ear. NeoZoline™ ventilation tubes are single-use and are sterilized by ethylene oxide.

NeoZoline™ ventilation tubes are made of different materials with different designs. The medial flange size and ventilation tube design will determine to a large extent how long the ventilation tube will remain in situ (stay inserted). Other factors that determine duration of placement include placement, the patients physiological response and surgical removal.

Instructions for Use

a The pouch containing the ventilation tube case should be opened aseptically.

b The label on the case containing the ventilation tube may be removed and used in patient records.

c Because the ventilation tube packaging materials are plastic, the ventilation tube may pick up an electrostatic charge. Upon opening the package, the ventilation tube should be carefully examined to ensure that particles have not been attracted to it.

d Gloves should not be dusted with powder and powderless gloves are recommended as the ventilation tubes may have an affinity for particulate matter. Under no circumstances should the ventilation tube make contact with powdered gloves, as the glove powder might provoke a foreign body reaction with granulation formation.

e Contents sterile unless the pouch seal is broken or package penetrated.

Contraindications

- Patients where drug treatment will suffice.
- Where in the surgeon's opinion surgical incision (myringotomy) of the tympanic membrane or aspiration of middle ear through the tympanic membrane without insertion of ventilation tubes will be sufficient.
- Ongoing middle ear infection.
- When adverse effects may be expected

Possible Adverse Effects to Ventilation Tubes

- Early extrusion or expulsion of the ventilation tube.
- Airborne or water contaminants entering through the ventilation tube may result in further infection.
- Ventilation tube may become clogged or blocked and cease to function.
- Certain ventilation tube materials may cause increased tissue irritation due to increased patient allergy or sensitivity.
- Grafting procedures may be required with permanent and/or consistent perforations of the tympanic membrane.

Warnings and Cautions

- Do not re-use ventilation tubes.
- Do not re-sterilize the ventilation tube if the case is opened.
- Do not implant the ventilation tube if the pouch which maintains sterility has been previously opened or damaged.
- After insertion of a ventilation tube fluid should be prevented from entering the ear to avoid contamination and infection.
- It is often difficult to determine if complications occurring after insertion of otological ventilation tubes are due to the ventilation tubes or are due to sequelae of the intrinsic disease. Occasionally otological ventilation tubes may contribute to a number of post-operative complications including: secondary infection accompanied by otorrhea through the tube, permanent perforations, dislocation of the tube into the middle ear cavity, tympanosclerosis, and localised or diffuse membrane atrophy.
- US Federal law restricts this device to sale and use by or on the order of a physician. Ventilation tubes are only to be inserted by qualified personnel.

Adept Medical Ltd shall not be liable for any injury or damage suffered by a patient as a result of: a) Any method of implantation or technique used by the surgeon to implant or use NeoZoline products. b) Any selection, prescription or use of NeoZoline products for any patient or condition. Adept Medical Ltd makes no expressed or implied warranties in connection with the sale of its products and specifically disclaims liability upon use or misuse.

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Appendix 7

Product Comparison

Product Comparison – Ventilation Tubes
Predicate Device Labelling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

ADEPT MEDICAL

Product Comparison - Ventilation Tubes

Issue Number 3 Reviewed
Issue Date 15/3/2006 Approved

COPY

Manufacturer	Product Code	Description	Inner Diameter	Inner Flange Diameter	Outer Flange Diameter	Inter Flange Distance	Length	Material	Feature
NeoZoline	**NZ3111**	Collar Button	1.27	3.0	3.0	1.55	2.15	Fluoroplastic	
NeoZoline	**NZ3112**	Collar Button - Tail	1.27	3.0	3.0	1.55	2.15	Fluoroplastic	Tail
Entermed	904820	Sheehy Type Collar Button	1.27	3.2	3.2	1.5	2.0	Fluoroplastic	
Gyrus ENT	14-5214	Collar Button	1.27	1.65		1.5		Fluoroplastic	
Gyrus ENT	14-5217	Collar Button	1.27	1.65		1.5		Fluoroplastic	Wire
Medtronic Xomed	10-28040	Sheehy Type Collar Button	1.27	3.0		1.55		Fluoroplastic	
Micromedics	VT-1000	Collar Button	1.27	2.9	2.9	1.4	2.1	Fluoroplastic	Wire
Micromedics	VT-1001	Collar Button	1.27	2.9	2.9	1.4	2.1	Fluoroplastic	
NeoZoline	**NZ3121**	Armstrong	1.14	2.5/3.5	2.5		3.8	Fluoroplastic	45° Angle
NeoZoline	**NZ3122**	Armstrong - Tail	1.14	2.5/3.5	2.5		3.8	Fluoroplastic	Tail, 45° Angle
Atos Medical	**7038**	Armstrong Type - Grommet	1.1	2.6			3.8	Fluoroplastic	Tab
Entermed	904840	Armstrong Belveled Grommet	1.10		2.5		4.0	Fluoroplastic	
Gyrus ENT	14-0242	Armsrtong Beveled Vent Tube Grommet	1.14	2.7	2.7		3.3	Fluoroplastic	15°Angle
Medtronic Xomed	10-10030	Armstrong Beveled Grommet Vent Tube	1.14	2.5/3.5	2.5		3.8	Fluoroplastic	45° Angle
Micromedics	VT-0503	Armstrong Grommet	1.14	2.5	2.4		4.0	Fluoroplastic	
NeoZoline	**NZ3123**	Modified Armstrong	1.14	2.5	2.5		2.3	Fluoroplastic	22.5° Angle
NeoZoline	**NZ3124**	Modified Armstrong - Tail	1.14	2.5	2.5		2.3	Fluoroplastic	Tail, 22.5° Angle
Medtronic Xomed	10-10170	Modified Armstrong Beveled Grommets	1.14	3.5	2.5		3.8	Fluoroplastic	45° Angle
Micromedics	VT-0508	Modified Armstrong Grommet	1.14	2.59/3.07	2.59	1.29	3.07	Fluoroplastic	
NeoZoline	**NZ3141**	Bevel Bobbin	1.14	2.8	2.8		1.7	Fluoroplastic	
Atos Medical	7013	Bevel Bobbin Type	1.15		2.8		1.8	Fluoroplastic	
Entermed	904805	Bevel Bobbin	1.14	2.8	2.8		1.7	Fluoroplastic	
Medtronic Xomed	10-56179	Beveled Bobbins	1.14					Fluoroplastic	
Micromedics	VT-0608	Bevel Bobbin	1.14	2.79	2.79		1.75	Fluoroplastic	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

ADEPT MEDICAL

Product Comparison - Ventilation Tubes

Issue Number 3 Reviewed
Issue Date 15/3/2006 Approved

Manufacturer	Product Code	Description	Inner Diameter	Inner Flange Diameter	Outer Flange Diameter	Inter Flange Distance	Length	Material	Feature
NeoZoline	**NZ3151**	Straight Tube	1.14	2.7			7.25	Fluoroplastic	
Exmoor	E1013	Cylindrical Vent Tube	1.14	2.45			7.11	Fluoroplastic	
Grace Medical Inc	520081	Straight Tube	1.14	2.30			7.00	Fluoroplastic	
Gyrus ENT	140035	Straight Vent Tube	1.14				7.0	Fluoroplastic	
Medtronic Xomed	10-28050	Plain Straight Shanks	1.14	2.75			7.0	Fluoroplastic	
Micromedics	VT-0910	Spooner	1.19	2.6			7.3	Fluoroplastic	
								Fluoroplastic	
NeoZoline	**NZ3211**	Collar Button	1.14	2.6	2.6	1.05	1.65	Fluoroplastic	
NeoZoline	**NZ3212**	Collar Button - Tail	1.14	2.6	2.6	1.05	1.65	Fluoroplastic	Tail
Exmoor	E.1011	Reuter Bobbins	1.14	2.54	2.54	0.76	1.52	Fluoroplastic	
Gyrus ENT	14-5213	Reuter Bobbin	1.14			1.0		Fluoroplastic	
Gyrus ENT	14-5224	Reuter Bobbin	1.14			1.0		Fluoroplastic	Wire
Medtronic Xomed	10-27005	Reuter Bobbins	1.14	2.6		1.0		Fluoroplastic	
Micromedics	VT-1204	Reuter Bobbin	1.14	2.8	2.8	1.0	1.5	Fluoroplastic	
NeoZoline	**NZ3213**	Shepard	1.14	2.4	2.4		2.2	Fluoroplastic	
NeoZoline	**NZ3214**	Shepard - Tail	1.14	2.4	2.4		2.2	Fluoroplastic	Tail
Gyrus ENT	145002	Shepard Grommet Vent Tube W/O Wire Tab	1.00					Fluoroplastic	
Medtronic Xomed	10-28020	Shepard Grommet Vent Tube	1.14					Fluoroplastic	
Micromedics	VT-0201	Shepard	1.14	2.4	2.4	1.6	2.4	Fluoroplastic	Wire
Micromedics	VT-0202	Shepard	1.14	2.4	2.4	1.6	2.4	Fluoroplastic	
Micromedics	VT-0204	Shepard	1.00	2.4	2.4	1.6	2.4	Fluoroplastic	
NeoZoline	**NZ3216**	Donaldson Short Term	1.10	2.4	2.4	0.8	2.4	Silicone	
Gyrus ENT	24-0015	Donaldson	1.14					Silicone	
Medtronic Xomed	10-13020	Donaldson Type Tube	1.14					Silicone	
Micromedics	VT-0100	Donaldson	1.14	2.4	2.4	0.8	2.2	Silicone	
Micromedics	VT-0101	Donaldson	1.14	2.4	2.4	0.8	2.2	Silicone	Tab

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ADEPT MEDICAL

Product Comparison - Ventilation Tubes

Issue Number 3 Reviewed AB
Issue Date 15/3/2006 Approved

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Manufacturer	Product Code	Description	Inner Diameter	Inner Flange Diameter	Outer Flange Diameter	Inter Flange Distance	Length	Material	Feature
NeoZoline	**NZ3217**	Paparella	1.10	3.3	2.5	0.8	1.8	Silicone	Notch
Gyrus ENT	24-0043	Paparella Type	1.02					Silicone	Notch
Medtronic Xomed	10-25001	Paparella Type	1.14	2.4		1.1		Silicone	Notch & Tab
Medtronic Xomed	10-12010	Paparella Type	1.14	4.3		0.85		Silicone	Membrane
Micromedics	VT-0300	Paparella Type I	1.14	2.4	2.1	1.1	2.2	Silicone	
NeoZoline	**NZ3218**	Paparella	1.40	3.8	3.0	0.9	1.8	Silicone	Notch
Medtronic Xomed	10-25045	Paparella Type	1.52					Silicone	Notch & Tab
Micromedics	VT-0301	Paparella Type II	1.42	2.4	2.7	1.1	2.2	Silicone	
NeoZoline	**NZ3219**	Collar Button	1.27	2.7	2.7	1.0	1.6	Fluoroplastic	
Entermed	904820	Sheehy Type Collar Button	1.27	3.2	3.2	1.5	2.0	Fluoroplastic	
Gyrus ENT	14-5214	Collar Button	1.27	1.65		1.5		Fluoroplastic	
Gyrus ENT	14-5217	Collar Button	1.27	1.65		1.5		Fluoroplastic	Wire
Medtronic Xomed	10-28040	Sheehy Type Collar Button	1.27	3.0		1.55		Fluoroplastic	
Micromedics	VT-1000	Collar Button	1.27	2.9	2.9	1.4	2.1	Fluoroplastic	Wire
Micromedics	VT-1001	Collar Button	1.27	2.9	2.9	1.4	2.1	Fluoroplastic	
NeoZoline	**NZ3220**	Reuter Long Term	1.27	3.7	3.7	1.0	1.6	Fluoroplastic	
Gyrus ENT	14-5019	Reuter Bobbin	1.14					Fluoroplastic	without Holes
Medtronic Xomed	10-27000	Reuter Bobbins	1.14	2.6		1.0		Fluoroplastic	
Medtronic Xomed	10-27005	Reuter Bobbins	1.14	2.6		1.0		Fluoroplastic	without Holes
Micromedics	VT-1204	Reuter Bobbin	1.14	2.8	2.8	1.0	1.5	Fluoroplastic	
Micromedics	VT-1203	Reuter Bobbin	1.00	2.8	2.8	1.0	1.5	Fluoroplastic	
Micromedics	VT-1202	Reuter Bobbin	1.00	2.8	2.8	1.0	1.5	Fluoroplastic	Holes
NeoZoline	**NZ3223**	Shah Mini	0.76	2.2	0.5		1.5	Fluoroplastic	
NeoZoline	**NZ3226**	Shah Mini - Tail	0.76	2.2	0.5		1.5	Fluoroplastic	Tail
Gyrus	14-2230	Shah	0.76					Fluoroplastic	
Medtronic Xomed	1431-1	Shah Type	0.76			1.0		Fluoroplastic	
Micromedics	VT-0805	Shah	0.76	1.7	1.7		2.0	Fluoroplastic	Wire

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ADEPT MEDICAL

Product Comparison - Ventilation Tubes

Issue Number 3 Reviewed
Issue Date 15/3/2006 Approved

Manufacturer	Product Code	Description	Inner Diameter	Inner Flange Diameter	Outer Flange Diameter	Inter Flange Distance	Length	Material	Feature
NeoZoline	**NZ3224**	Shah	1.14	3.4	0.8		2.4	Fluoroplastic	
NeoZoline	**NZ3227**	Shah - Tail	1.14	3.4	0.8		2.4	Fluoroplastic	Tail
Gyrus	14-6044	Shah	1.14					Fluoroplastic	
Gyrus	14-0005	Shah	1.14					Fluoroplastic	Wire
Medtronic Xomed	10-28030	Shah Type	1.14			1.58		Fluoroplastic	
Medtronic Xomed	10-28035	Shah Type	1.14			1.58		Fluoroplastic	Wire
Micromedics	VT-0804	Shah	1.14	2.4	2.4		2.5	Fluoroplastic	
Micromedics	VT-0802	Shah	1.14	2.4	2.4		2.5	Fluoroplastic	Tab

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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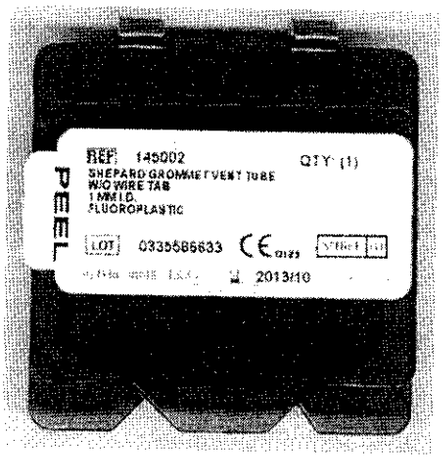
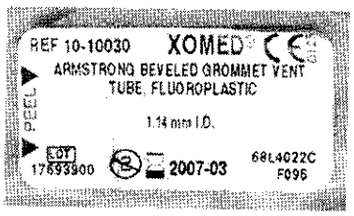
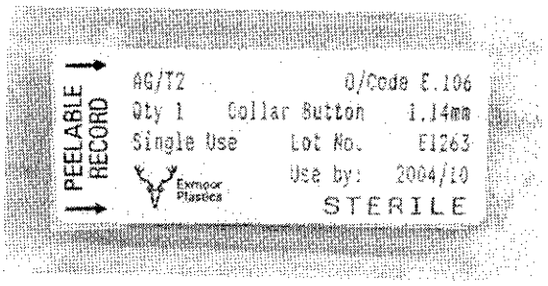
Product Labelling







Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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User Instructions

Otologic Ventilation Tubes

Before using, read the following information

DESCRIPTION:
The implant is placed in the tympanic membrane through an incision for the ventilation of the middle ear space. Implants are manufactured with a variety of materials such as silicone elastomer, biomaterials, stainless steel or titanium. Designs utilize single or dual flanges.

INDICATIONS:
Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.

CONTRAINDICATION:
None known. This device is not designed, sold, or intended for use except as indicated or prescribed by a physician.

PRECAUTIONS:
Avoid fluid contact with ear.

POSSIBLE ADVERSE EFFECTS:
Tube may clog
Persistent perforations of the tympanic membrane
Granulomatosis
Premature extrusion
Failure to self-extrude
Infection due to airborne or water contamination

STERILITY:
Contents sterile unless package is damaged or open. Peel pouch open from corner using sterile technique.

PRODUCT RECORD LABELS:
Adhesive product labels are included in package for use on patient and hospital records.

CAUTION:
EFFECTS OF MRI ON METALLIC VENTILATION TUBES AND VENTILATION TUBES WITH METALLIC COMPONENTS
Micromedics manufactures its metal ventilation tubes only from titanium alloys and non-magnetic medical grade stainless steel demonstrated to be unaffected by the strong magnetic fields produced by MRI units. Stringent quality controls measures have been established by Micromedics to ensure only non-ferromagnetic metals are used in manufacturing of metallic ventilation tubes; *HOWEVER*, caution is advised when administering MRI procedures. Always consult MRI manufacturers instructions.

Authorized EU representative:
Peter J. Smith
Crown House
Hornbeam Square North
Harrowgate HG2 8PB U.K.

Manufactured by:
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(800)-624-5662 (USA Only)
FAX 1-888-504-0606
www.micromedics-usa.com

CE 0123 *Rx Only* (U.S.A)

20010 Rev.D

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 8

Quality System Certificates

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SGS

Certificate GB04/63721

The management system of

Adept Medical Ltd

6 McDonald Street, Morningside,
Auckland, New Zealand

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

Annex II (excluding Section 4) and
Annex V (sterility aspects only)

For the following activities

Annex II (excluding Section 4)
Sterile middle ear suction tube kit consisting of suction tubes and controllers,
Sterile suction controller,
Sterile myringotomy knife,
Sterile blunt needle grommet inserter,
Sterile tympanostomy tubes both rigid and soft,
Sterile septal nasal splint.

Annex V (sterility aspects only)
Myringotomy kits,
Sterile ear curettes,
Sterile ear speculae.

This certificate is valid from 23 December 2004 until 23 December 2008
Issue 1. Certified since 23 December 2004

Notified Body Number 0120
Authorised by

CE
0120

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0303

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SGS

Certificat(e) CA05/3421

The management system of
Le système de gestion de

Adept Medical Ltd.

6 McDonald Street
Morningside, Auckland, New Zealand

has been assessed and certified as meeting the requirements of:
a été évalué et enregistré selon les exigences de la norme:

ISO 13485:1996

SYSTEM CERTIFICATION
CERTIFICATION DE SYSTÈMES
ISO 13485
SGS

The scope of registration is as follows:
La portée d'enregistrement est:

Design and manufacture of sterile and non sterile tympanostomy tubes both rigid and soft, ear curettes, ear speculae, myringotomy knives, suction tubes, suction controllers and blunt needle grommet inserters, video otoscope clip-on curettes and sterile septal nasal splints and non sterile external nasal splints.

This certificate is valid from January 24, 2005 until July 15, 2006
Ce certificat est valide du 24 janvier, 2005 au 15 juillet, 2006
Issue 1.
Édition 1.

Signed for and on behalf of SGS Systems & Services Certification Canada Inc.
Document signé pour et au nom de SGS Certification de Systèmes & Services Canada Inc.

Standards Council of Canada
Accredited Registrar
Conseil canadien des normes
Registraire accrédité
TM

Certification Manager: John Pettitt
Directeur de Certification: John Pettitt
SGS Systems & Services Certification Canada Inc.
SGS Certification de Systèmes & Services Canada Inc.
6275 Northam Drive, Unit 2, Mississauga, Ontario, L4V 1Y8 Canada
t (905) 676-9595 t 1-800-636-0847 f (905) 676-9519 www.sgs.com

CMDCAS Recognized Registrar.
Registraire reconnu selon le CMDCAS.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SGS

Certificate GB04/63722

The management system of

Adept Medical Ltd

6 McDonald Street, Morningside,
Auckland, New Zealand

SYSTEM CERTIFICATION ISO 13485 SGS

has been assessed and certified as meeting the requirements of

ISO 13485:1996

For the following activities

Design and manufacture of sterile and non sterile tympanostomy tubes both rigid and soft, ear curettes, ear speculae, myringotomy knives, section tubes, suction controllers and blunt needle grommet inserters, video otoscope clip-on curettes and sterile septal nasal splints and non sterile external nasal splints.

This certificate is valid from 23 December 2004 until 15 July 2006
Issue 1. Certified since 23 December 2004

Authorised by

UKAS QUALITY MANAGEMENT 005

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-1 0803

SGS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Appendix 9

Clinical Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Trade Secret Process -Clinical Evaluation Report

(b)(4) Trade Secret Process -Clinical Evaluation Report

(b)(4) Trade Secret Process -Clinical Evaluation Report

(b)(4) Trade Secret Process -Clinical Evaluation Report

(b)(4) Trade Secret Process -Clinical Evaluation Report

(b)(4) Trade Secret Process -Clinical Evaluation Report

(b)(4) Trade Secret Process -Clinical Evaluation Report

(b)(4) Trade Secret Process -Clinical Evaluation Report

(b)(4) Trade Secret Process -Clinical Evaluation Report

Records processed under FOIA Request 2014-1543; Released 11/12/14

Appendix 10

Biocompatibility

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Trade Secret Process - Biocompatibility Report

(b)(4) Trade Secret Process - Biocompatibility Report

(b)(4) Trade Secret Process - Biocompatibility Report

(b)(4) Trade Secret Process - Biocompatibility Report

(b)(4) Trade Secret Process - Biocompatibility Report

(b)(4) Trade Secret Process - Biocompatibility Report

Records processed under FOIA Request 2014-1543; Released 11/12/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Karen A Baker

Subject: 510(k) Number K061058 / S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☐ A 510(k) summary OR ☑ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 874.3880 ETD Class II

Additional Product Code(s) with panel (optional):

Review: [signature] (Branch Chief) ENT B (Branch Code) 6/12/06 (Date)

Final Review: [signature] for MDS (Division Director) 7/12/06 (Date)

Revised:4/2/03

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Document # K061058

Company Name: Adept Medical Co.

Contact Person: Jason Marsh
Quality System Manager
Adept Medical
2 McDonald Street
Morningside
Auckland, New Zealand 1003
09-8152999
09-8466976 fax
jmarsh@adept.co.nz

Device Name: Neozoline Ventilation Tubes
Classification name: Tube, Tympanostomy
CFR 984.3880, Class II, Product Code ETD

Common name: Tympanostomy Tubes

Product to which compared: The subject tympanostomy tubes are compared to a variety of previously cleared tubes from several manufacturers. These include: Medtronic Xomed, Atos Medical, Micromedics, Gyrus ENT, and Exmoor. These devices have been marketed in various materials, including fluoroplastic for many years.

Intended Use Statement: An otological ventilation tube is a device that is intended to be implanted for ventilation and/or drainage of the middle ear.

Submission Provides:

Comparative Specifications:	yes
Comparative Lab Data:	no
Summary of Animal Testing:	no
Summary of Clinical Testing:	no
510(K) Statement:	yes

GENERAL INFORMATION SUMMARY

Life-Supporting or Life-Sustaining:	no
Is it an Implant?	yes
Software Driven	no
Sterility	yes
Single Use:	yes
Home or prescription use:	yes
Drug or Biologic product:	no
Device a kit:	no

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

	YES	NO	
1. IS PRODUCT A DEVICE?	x		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	x		- IF NO STOP
3. SAME INDICATION STATEMENT?	x		- IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP, NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	x		- IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	x		~~- IF NO GO TO 10~~ - IF YES STOP Se
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP, NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP, NE - IF NO, REQUEST DATA
10. PERFORMANCE DATA AVAILABLE?			
11. DATA DEMONSTRATE EQUIVALENCE?			

Device Description: Tympanostomy tubes (of various configurations) have been used for many years in the treatment of otitis media and middle ear effusion by otolaryngologists. The safety and effectiveness of these devices is well established in the medical community.

NeoZoline™ Otological Ventilation Tubes include of number of different models which differ in design, material and size. The models include: Collar Button; Shepard; Sheehy Collar; Reuter; Shah; Armstrong; Bevel Bobbin: and Straight Tube. Some models feature a "tail" which is used to assist with removal of the tube. The sponsor provides product drawings for each of the models. The proposed designs are similar to those legally marketed in the United States.

(b)(4) Trade Secret Process

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

(b)(4) Trade Secret Process

Physical Properties and Performance Testing: The physical properties are described in terms of size, shape, physical dimensions, material, and packaging. The configurations of the various models are either very similar or identical to many other ventilation tubes currently marketed.

The sponsor lists the applicable standards which are primarily sterilization, packaging biological evaluation of medical device standards. He also states compliance with ISO 13485:1996 Quality System Regulation; European Union Medical Device Directive; Canadian Medical Devices Regulations; and, Australian Therapeutic Goods Regulations.

Device Labeling: Sample labeling is provided. User instructions include: Instructions for use, contraindications, warnings and cautions, and possible adverse effects.

Sterilization: The devices are provided sterile. The sterilization method is 100%. The validation is in accordance with ISO 11135:1994, Medical devices-Validation and Routine Control of Ethylene Oxide Sterilization. ETO residual testing is in accordance with ISO 10993-7-1995. Bioburden testing and validation test results were satisfactory and in compliance with USP 27 Biological Tests, Bacterial Endotoxin Test.

(b)(4) Trade Secret Process

Clinical: (b)(4) Trade Secret Process

Summary: The outstanding question regarding the biocompatibility of the materials is satisfactorily addressed.

Recommendation: The Adept Medical Neozoline tympanostomy tubes are substantially equivalent to other legally marketed tympanostomy tubes.

Karen H. Baker, MSN, RN
Nurse Consultant, ENTB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

REVIEW OF TOXICOLOGY DATA

(b)(4) Trade Secret Process

[redacted]

CONCLUSION

The company submitted adequate information to show that the patient contact material in this device will not cause any adverse effect during the intended use. I have no further questions to the sponsor.

Vasant G. Malshet, Ph.D., DABT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Karen Baker

Subject: 510(k) Number K061058

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Telephone Hold

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☐ Enclosed

☐ A 510(k) summary OR ☑ A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☑ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

874.3880 Class II ETD

Review: [signature] (Branch Chief) ENT (Branch Code) 5/11/06 (Date)

Final Review: [signature] (Division Director) 5/11/06 (Date)

Revised:4/2/03

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		X
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?		
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K061058

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☒ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement. included - not signed		✓
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.		✓
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement. included - not signed		✓
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	N/A	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard**, which is posted with the 510(k) boilers on the **H drive.**]		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL		✓
iv) packaging	✓	
v) specify pyrogen free		✓
vi) ETO residues	✓	
vii) radiation dose	N/A	
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:	✓	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening: ✓ Yes ___ No

Reviewer: [illegible]

Concurrence by Review Branch: [illegible]

Date: 5/9/06

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Baker, Karen

:om: Baker, Karen
ɔent: Tuesday, May 09, 2006 2:31 PM
To: 'jmarsh@adept.co.nz'
Subject: K061058

Attachments: Picture (Metafile)

Mr. Marsh,

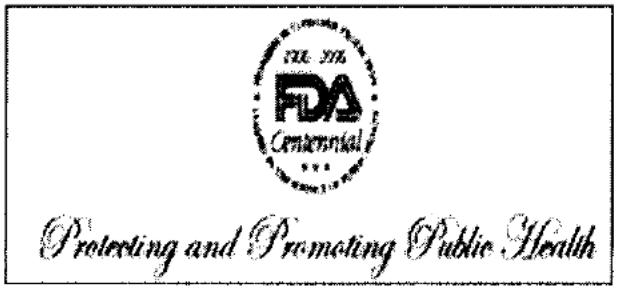
(b)(4) Trade Secret Process

[redacted]

Please call or e-mail me if you have any questions.

Karen Baker

Karen Baker, MSN, RN
Nurse Consultant
Ear, Nose and Throat Devices Branch
ɔED/ODE/CDRH/FDA
.01-594-2080
301-594-2339 (fax)
karen.baker@fda.hhs.gov



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

REVIEW OF TOXICOLOGY DATA

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

Vasant G. Malshet, Ph.D., DABT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14 .

Indications for Use

510(k) Number (if known): K061058

Device Name: Neozoline Ventilation Tubes

Indications For Use:

The largest patient population are children between 4 months and 6 years of age (but not exclusively). Otological ventilation tubes are indicated for patients with:

- Chronic or recurrent otitis media with persistent effusion (OME).
- Recurrent acute otitis media.
- Acute otitis media with complications.
- Eustachian tube dysfunction resulting in one or more of the following: significant and symptomatic hearing loss, otalgia, vertigo, and tinnitus.
- Hearing loss resulting from bilateral chronic middle ear effusion.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND/OR~~ Over-The-Counter Use ___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

4 **510(K) Statement**:

(As required by 21 CFR 807.93)

I certify that in my capacity as an official correspondent/Quality Systems Manager of Adept Medical Limited, I will make available all information included in the premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent.

The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patent identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Signature of Certifier

Typed Name

Jason Marsh

Date

10/04/06

Premarket Notification 510 (K) Number

K061058

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

5 **Truthful & Accurate Statement**:

(As required by 21 CFR 807.87 [K])

I certify that in my capacity as Quality Systems Manager of Adept Medical Limited, I believe to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material has been omitted.

Signature of Certifier

Typed Name

Jason Marsh

Date

10/04/06

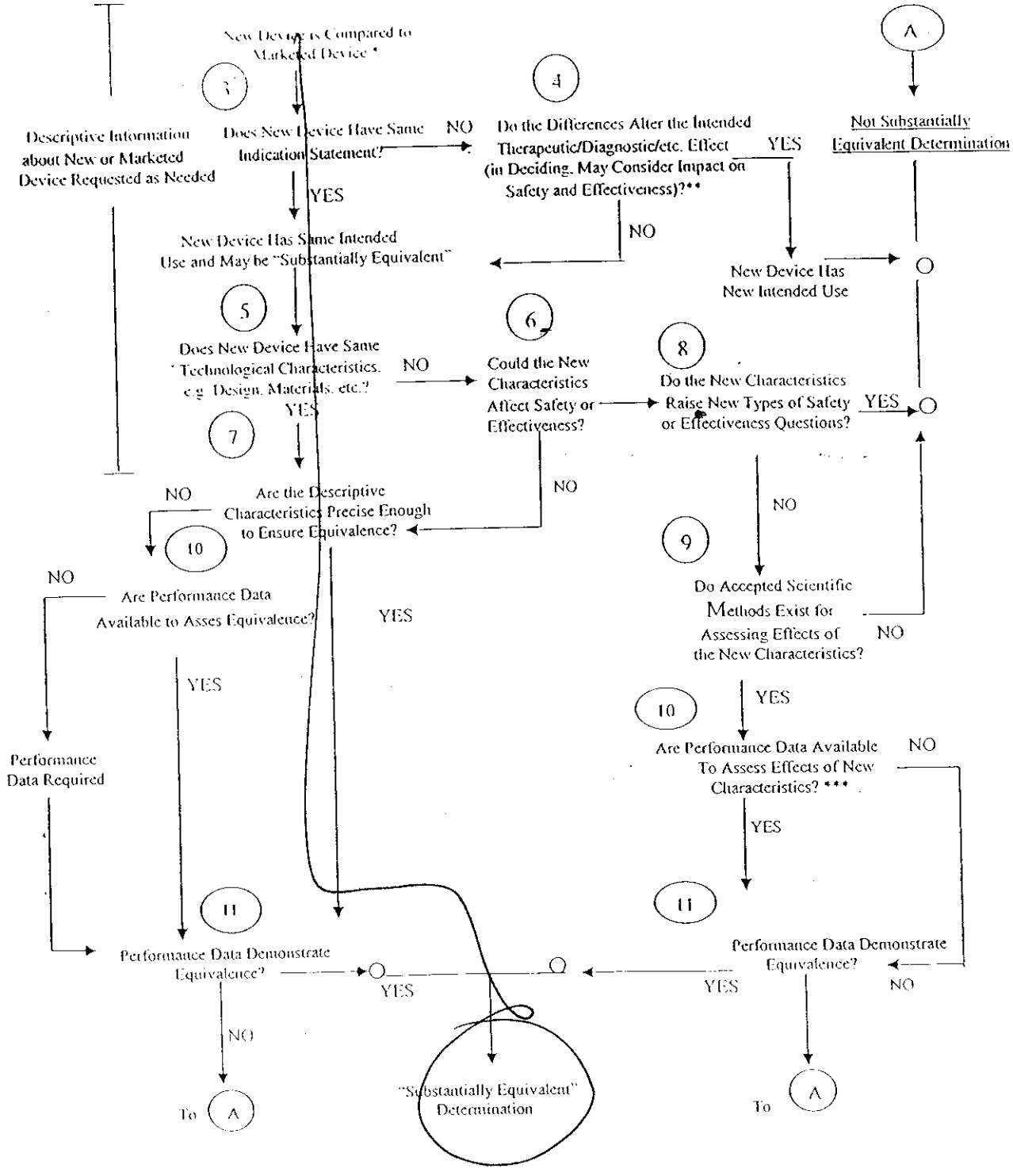
Premarket Notification 510 (K) Number

K061058

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
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9200 Corporate Blvd.
Rockville, Maryland 20850

June 19, 2006

ADEPT MEDICAL LTD
2 MCDONALD STREET, MORNINGSIDE
AUCKLAND,
NEW ZEALAND 1003
ATTN: JASON MARSH

510(k) Number: K061058
Product: NEOZOLINE VENTILATION TUBES

(b)(4) Trade Secret Process

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Trade Secret Process

[redacted]

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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K061058/S1

Adept Medical Limited
6 McDonald St, Morningside
PO Box 10075, Dominion Rd
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www.adeptmedical.co.nz

ADEPT
MEDICAL

REF: 20060608

16 June 2006

Karen Baker, MSN, RN
Nurse Consultant
Ear, Nose and Throat Devices Branch
DOED/ODE/CDRH/FDA

FDA/CDRH/OCE/DID
2006 JUN 19 A 10: 52

Re: 510(k) Number K061058

Dear Ms Baker

(b)(4) Trade Secret Process

[redacted]

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(b)(4) Trade Secret Process

[redacted]

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(b)(4) Trade Secret Process

[redacted]

Yours sincerely

Anthony Blyth

Anthony Blyth

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Appendix A

Sales History of NeoZoline™ Fluoroplastic Otological Ventilation Tubes

Unit Sales for Financial Years (April to March) 1990 to 2006

	F1990 – F1994*	F1995*	F1996	F1997	F1998	F1999
Asia Pacific	Between 2000 and 9000 pa	8,250	8,460	9,230	11,340	9,040
Europe	-	-	-	-	-	
Total	Between 2000 and 9000 pa	8,250	8,460	9,230	11,340	9,040

* New Zealand only

	F2000	F2001	F2002	F2003	F2004	F2005	F2006
Asia Pacific	14,680	13,850	11,840	11,380	12,060	13,430	12,240
Europe	-	-	-	-	-	4,000	13,910
Total	14,680	13,850	11,840	11,380	12,060	17,430	26,150

Total Sales for F1995 to F2006 = 153,710

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Appendix B

Essential Requirements Conformity Checklist - Otological Ventilation Tubes

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CHECKLIST OF COMPLIANCE WITH ESSENTIAL REQUIREMENTS OF THE MEDICAL DEVICE DIRECTIVE (MDD), 12 JULY 1993, 93/42/EEC, ANNEX I

Adept Medical Limited	Checklist completed by (name): Anthony Blyth	Date: 30 August 2005

Product / Product Group:
Otological Ventilation Tubes

Product Codes:
NZ3111, NZ3112, NZ3121, NZ3122, NZ3123, NZ3124, NZ3141, NZ3151, NZ3211, NZ3212, NZ3213, NZ3214, NZ3216, NZ3217, NZ3218, NZ3219, NZ3220, NZ3223, NZ3224, NZ3226, NZ3227

Description:
Otological Ventilation Tubes (Various Designs)

Intended Use/Purpose:
An otological ventilation tube is a device that is intended to be implanted for ventilation and/or drainage of the middle ear.

Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
I General Requirements			
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes	Adept Medical's Quality Management System complies with recognised and international standards and is verified through independent audit by a Conformity Assessment Body.	- ISO 13485:1996 - Quality Systems – Medical Devices Particular Requirements for the Application of ISO 9001. - ISO 13485:1996 Certificate issued by SGS United Kingdom Limited - ISO 14969:1999 - Guidance on the Application of ISO 13485

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
		Product Risk Management complies with recognised standard.	and 13488 to medical devices. - Adept Medical's Quality Manual. - ISO 14971:2000 - Application of Risk Management to Medical Devices. - Adept Medical Procedure M11-01, Product Risk Management. - Risk Management Numbers 0008, 0009, 0010, 0011, 0013, 0018
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction), - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	Yes	Design and manufacture complies with Adept Medical's internal documented systems.	- ISO 13485:1996 - Quality Systems – Medical Devices Particular Requirements for the Application of ISO 9001. - ISO 13485:1996 Certificate issued by SGS United Kingdom Limited - GHTF document SG3/N99-9 Design Control Guidance for Medical Device Manufacturers - Adept Medical's Quality Manual. - Adept Medical Procedure M10-01, Product Development - Adept Medical Procedure M12-

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
- inform users of the residual risks due to any shortcomings of the protection measures adopted.			04, Manufacturing Process Validation - Manufacturing Process Validation 001, 003, 006, 011
		Product Risk Management complies with recognised standard.	- ISO 14971:2000 – Application of Risk Management to Medical Devices. - Adept Medical Procedure M11-01, Product Risk Management. - Risk Management Numbers 0008, 0009, 0010, 0011, 0013, 0018
		Labelling complies with recognised standard.	- EN 1041:1998 – Information Supplied by the Manufacturer with Medical Devices - GHTF document SG1/N009R6 Labelling for Medical Devices - Adept Medical Procedure M10-04, Labelling Requirements - Adept Medical product labels supplied with products
		No alarms required (Non-active device).	

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	Yes	Design and manufacture complies with Adept Medical's internal documented systems.	- ISO 13485:1996 - Quality Systems – Medical Devices Particular Requirements for the Application of ISO 9001. - ISO 13485:1996 Certificate issued by SGS United Kingdom Limited - GHTF document SG3/N99-9 Design Control Guidance for Medical Device Manufacturers - Adept Medical's Quality Manual. - Adept Medical Procedure M10-01, Product Development - Adept Medical Procedure M12-04, Manufacturing Process Validation - Manufacturing Process Validation 001, 003, 006, 011
		Performance claims consistent with verification documents.	- Adept Medical Procedure M09-09, Clinical Evaluation - Technical File - Clinical Evaluation – Ventilation Tubes
		Packaging meets criteria outlined in Technical Files	- EN 868-1:1997 Part 1: General Requirements and Test Methods

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
		and international standard	- GHTF document SG3/N99-9 Design Control Guidance for Medical Device Manufacturers - Adept Medical Quality Manual - Adept Medical Procedure M10-01, Product Development - Technical Files - Laboratory Report 002, 013
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	Yes	Adept Medical has a documented vigilance system procedure and post-market surveillance procedure. Management Review provides scrutiny of any product problems.	- Adept Medical Procedure M09-05-01, EU – Vigilence System. - Adept Medical Procedure M09-03, Post Market Surveillance

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Yes	Packaging meets criteria outlined in Technical Files and international standard	- EN 868-1:1997 Part 1: General Requirements and Test Methods - GHTF document SG3/N99-9 Design Control Guidance for Medical Device Manufacturers - Adept Medical Quality Manual - Adept Medical Procedure M10-01, Product Development - Adept Medical Procedure M12-04, Manufacturing Process Validation - Technical File - Laboratory Report 002, 013
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	Yes	Product Risk Management complies with recognised standard.	- ISO 14971 – Application of Risk Management to Medical Devices - Adept Medical Procedure M11-01, Product Risk Management. - Risk Management Numbers 0008, 0009, 0010, 0011, 0013, 0018
		Benefits identified and documented through review of clinical evaluation of the product and its competition	- Adept Medical Procedure M09-09, Clinical Evaluation - Technical File - Clinical Evaluation – Ventilation Tubes

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
II Requirements Regarding Design and Construction			
7 Chemical, physical and biological properties			
7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to: - the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, - the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.	Yes	Adept Medical's Quality Management System complies with recognised and international standards and is verified through independent audit by a Conformity Assessment Body. Flamability not a hazard for this product. Biocompatibility assessment complies with the recognised standard.	- ISO 13485:1996 - Quality Systems – Medical Devices Particular Requirements for the Application of ISO 9001. - ISO 13485:1996 Certificate issued by SGS United Kingdom Limited - ISO 14969:1999 – Guidance on the Application of ISO 13485 and 13488 to medical devices. - Adept Medical's Quality Manual. - EN ISO10993-1:1998 Biological evaluation of Medical Devices Part 1. - Technical File - Biological Safety Assessment – Ventilation Tubes

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	Yes	Biocompatibility assessment complies with the recognised standard. Packaging meets criteria outlined in Technical Files and international standard	- EN ISO10993-1:1998 Biological evaluation of Medical Devices Part 1. - Technical File - Biological Safety Assessment – Ventilation Tubes - EN 868-1:1997 Part 1: General Requirements and Test Methods - Adept Medical Procedure M12-04, Manufacturing Process Validation - Technical File - Manufacturing Process Validation 001 - Laboratory Report 002, 013
7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	Yes	Product Risk Management complies with recognised standard. Packaging meets criteria outlined in Technical Files	- ISO 14971:2000 - Application of Risk Management to Medical Devices. - Adept Medical Procedure M11-01, Product Risk Management. - Risk Management Numbers 0008, 0009, 0010, 0011, 0013, 0018 - EN 868-1:1997 Part 1: General Requirements and Test Methods

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
		and international standard Devices are not intended to be used to administer medicine.	- Adept Medical Procedure M12-04, Manufacturing Process Validation - Technical File - Manufacturing Process Validation 001 - Laboratory Report 002, 013
7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC.	No	Medicines not incorporated into the device.	
7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.	Yes	Biocompatibility assessment complies with the recognised standard.	- EN ISO10993-1:1998 Biological evaluation of Medical Devices Part 1. - Technical File - Biological Safety Assessment – Ventilation Tubes

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
7.6. Devices must he designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	Yes	Biocompatibility assessment complies with the recognised standard. Packaging meets criteria outlined in Technical Files and international standard	- EN ISO10993-1:1998 Biological evaluation of Medical Devices Part 1. - Technical File - Biological Safety Assessment – Ventilation Tubes - EN 868-1:1997 Part 1: General Requirements and Test Methods - Adept Medical Procedure M12-04, Manufacturing Process Validation - Technical Files - Manufacturing Process Validation 001 - Laboratory Report 002, 013
8 Infection and microbial contamination			
8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	Yes	Product Risk Management complies with recognised standard.	- ISO 14971 – Application of Risk Management to Medical Devices - Adept Medical Procedure M11-01, Product Risk Management. - Risk Management Numbers 0008, 0009, 0010, 0011, 0013, 0018

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
		Packaging meets criteria outlined in Technical Files and international standard	- EN 868-1:1997 Part 1: General Requirements and Test Methods - Adept Medical Procedure M12-04, Manufacturing Process Validation - Technical Files - Manufacturing Process Validation 001 - Laboratory Report 002, 013
8.2 Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must he carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	No	No materials of this type are incorporated into the product.	
8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile,	Yes	Devices are supplied in a sterile state and are validated.	- ISO 11135:1994 Medical Devices – Validation and routine control of ethylene oxide sterilisation

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
under the storage and transport conditions laid down, until the protective packaging is damaged or opened.			- Adept Medical Procedure M12-04, Manufacturing Process Validation - Manufacturing Process Validation 003 and 006 - Supplier GMP Agreement 0001
		Environmental conditions of manufacture are controlled through Adept Medical's quality management system and controls at the sub-contract sterilisation company. All procedures/systems subject to validation and testing.	- Adept Medical Procedure M16-01, Clean Room Operation document. - Adept Medical Procedure M07-03, Air Quality Validation document. - Manufacturing Process Validation 002, 007, 008
		Packaging meets criteria outlined in Technical Files and international standard	- EN 868-1:1997 Part 1: General Requirements and Test Methods - Adept Medical Procedure M12-04, Manufacturing Process Validation - Technical Files - Manufacturing Process Validation 001 - Laboratory Report 002, 013

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	Yes	Devices are supplied in a sterile state and are validated.	- SO 11135:1994 Medical Devices – Validation and routine control of ethylene oxide sterilisation - Adept Medical Procedure M12-04, Manufacturing Process Validation - Manufacturing Process Validation 003 and 006 - Supplier GMP Agreement 0001
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (c. g. environmental) conditions.	Yes	Environmental conditions of manufacture are controlled through Adept Medical's quality management system and controls at the sub-contract sterilisation company. All procedures/systems subject to validation and testing.	- Adept Medical Procedure M16-01, Clean Room Operation document. - Adept Medical Procedure M07-03, Air Quality Validation document. - Manufacturing Process Validation 002, 007, 008
8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Yes	Environmental conditions of manufacture are controlled through Adept Medical's quality management system and controls at the sub-contract sterilisation company. All	- Adept Medical Procedure M16-01, Clean Room Operation document. - Adept Medical Procedure M07-03, Air Quality Validation document. - Manufacturing Process

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
		procedures/systems subject to validation and testing.	Validation 002, 007, 008
8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Yes	Labelling complies with recognised standard. Packaging meets criteria outlined in Technical Files and international standard	- EN 1041:1998 – Information Supplied by the Manufacturer with Medical Devices - GHTF document SG1/N009R6 Labelling for Medical Devices - Adept Medical Procedure M10-04, Labelling Requirements - Adept Medical product labels supplied with products - EN 868-1:1997 Part 1: General Requirements and Test Methods - Adept Medical Procedure M12-04, Manufacturing Process Validation - Technical Files - Manufacturing Process Validation 001 - Laboratory Report 002, 013

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
9 Construction and environmental properties			
9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	Yes	Devices can be safely used with other myringotomy accessories.	- Adept Medical Procedure M09-07, Technical Documentation. - Technical Files
9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: - the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features, - risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, - the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, - risks arising where maintenance or calibration are not	Yes	Product Risk Management complies with recognised standard. Devices are small and light. Devices are manufactured from non-magnetic materials. Devices are non-active. Devices are not calibrated.	- ISO 14971 – Application of Risk Management to Medical Devices - Adept Medical Procedure M11-01, Product Risk Management. - Risk Management Numbers 0008, 0009, 0010, 0011, 0013, 0018

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	No	Devices are non-active and do not channel flammable materials .	

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
10 Devices with a measuring function			
10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.	No	Devices do not have a measuring function.	
10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	No	Devices do not have a measuring function.	
10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).	No	Devices do not have a measuring function.	

1 OJ No L 39. 15. 2. 1980, p. 40. Directive as last amended by Directive 891617/EEC (OJ No L 357, 7.12.1989, p. 28).

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
11 Protection against radiation			
11.1. *General* 11.1.1 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	No	Devices do not emit radiation.	
11.2. *Intended radiation* 11.2.1 Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	No	Devices do not emit radiation.	
11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	No	Devices do not emit radiation.	

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
11.3. *Unintended radiation* 11.3.1 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	No	Devices do not emit radiation.	
11.4. *Instructions* 11.4.1 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	No	Devices do not emit radiation.	
11.5. *Ionizing radiation* 11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can he varied and controlled taking into account the intended use.	No	Devices do not emit radiation.	
11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	No	Devices do not emit radiation.	

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	No	Devices do not emit radiation.	
12 Requirements for medical devices connected to or equipped with an energy source			
12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	No	Devices are non-active.	
12.2. Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	No	Devices are non-active.	
12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	No	Devices are non-active.	

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	No	Devices are non-active.	
12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	No	Devices are non-active.	
12.6. *Protection against electrical risks* Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	No	Devices are non-active.	
12.7. *Protection against mechanical and thermal risks* 12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	No	There are no hazards of this type.	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	No	Devices do not vibrate.	
12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	No	Devices do not emit noise.	
12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	No	Devices are not connected to such energy supplies.	
12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply beat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal Use.	No	Devices do not generate heat.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
12.8. *Protection against the risks posed to the patient by energy supplies or substances* 12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	No	Devices do not supply energy.	
12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	No	Devices do not supply energy.	
12.9. The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	No	Devices do not incorporate indicators and controls.	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
13 Information supplied by the manufacturer			
13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set our on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set our in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	Yes	Labelling complies with recognised standard. Labelling and instructions provide warnings. Packaging meets international standard.	- EN 1041:1998 – Information Supplied by the Manufacturer with Medical Devices - GHTF document SG1/N009R6 Labelling for Medical Devices - Adept Medical Procedure M10-04, Labelling Requirements - Adept Medical product labels supplied with products. - EN 868-1:1997 Part 1: General Requirements and Test Methods - Adept Medical Procedure M12-04, Manufacturing Process Validation - Technical Files - Manufacturing Process Validation 001 - Laboratory Report 002, 013
13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	Yes	Labelling complies with recognised standard. Labelling and instructions provide warnings.	- EN 1041:1998 – Information Supplied by the Manufacturer with Medical Devices - GHTF document SG1/N009R6 Labelling for Medical Devices - Adept Medical Procedure M10-04, Labelling Requirements

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
			- Adept Medical product labels supplied with products.
13.3. The label must bear the following particulars: (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14 (2) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate; (b) the details strictly necessary for the user to identify the device and the contents of the packaging; (c) where appropriate, the word 'STERILE'; (d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number; (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; (f) where appropriate, an indication that the device is for single use; (g) if the device is custom-made, the words 'custom-made device'; (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	Yes	Labelling complies with recognised standard. Labelling and instructions provide warnings.	- EN 1041:1998 – Information Supplied by the Manufacturer with Medical Devices - GHTF document SG1/N009R6 Labelling for Medical Devices - Adept Medical Procedure M10-04, Labelling Requirements - Adept Medical product labels supplied with products.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
(i) any special storage and/or handling conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by (c). This indication may be included in the batch or serial number; (m) where applicable, method of sterilization.			
13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Yes	Labelling complies with recognised standard. Labelling and instructions provide warnings	- EN 1041:1998 – Information Supplied by the Manufacturer with Medical Devices - GHTF document SG1/N009R6 Labelling for Medical Devices - Adept Medical Procedure M10-04, Labelling Requirements - Adept Medical product labels supplied with products.
13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Yes	Labelling complies with recognised standard. Labelling and instructions provide warnings	- EN 1041:1998 – Information Supplied by the Manufacturer with Medical Devices - GHTF document SG1/N009R6 Labelling for Medical Devices - Adept Medical Procedure M10-04, Labelling Requirements - Adept Medical product labels supplied with products.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-1543; Released 11/12/14

Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
13.6. Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (c); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must he installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; (e) where appropriate, information to avoid certain risks in connection with implantation of the device; (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization; (h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of	Yes	Instructions for use comply with recognised standard.	- EN 1041:1998 – Information Supplied by the Manufacturer with Medical Devices - GHTF document SG1/N009R6 Labelling for Medical Devices - Adept Medical Procedure M10-04, Labelling Requirements - Adept Medical User Instructions.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied'with the intention that they be sterilized before. use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I; (i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: (k) precautions to be taken in the event of changes in the performance of the device; (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice 'of substances to be delivered;			

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Essential Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
(n) precautions to be taken against any special, unusual risks related to the disposal of the device; (o) medicinal substances incorporated into the device as an integral part in accordance with Section 7.4; (p) degree of accuracy claimed for devices with a measuring function.			
14 Clinical Evaluation			
14. Where conformity with the essential requirements must be based on clinical data, as in Section I (6), such data must be established in accordance with Annex X.	Yes	Clinical Evaluation including clinical literature review, market experience and review of competitor devices has been documented and is available to the Regulatory Authorities if required. It is sufficient in itself and further testing of the medical device is not required.	- MEDDEV 2.7.1 – Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies. - Adept Medical Procedure M09-09, Clinical Evaluation - Clinical Evaluation – Ventilation Tubes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Adept Medical Limited
6 McDonald St, Morningside
PO Box 10075, Dominion Rd
Auckland New Zealand

Telephone +64 9 815 2999
Facsimile +64 9 846 6976
www.adeptmedical.co.nz

ADEPT
MEDICAL

REF: 20060608

Appendix C

Directive 93/42/EEC Certificate

and

ISO 13485:2003 CMDCAS Certificate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SGS

Certificate GB04/63721

The management system of

Adept Medical Ltd

6 McDonald Street, Morningside,
Auckland, New Zealand

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

Annex II (excluding Section 4) and
Annex V (sterility aspects only)

For the following activities

Annex II (excluding Section 4)
Sterile middle ear suction tube kit consisting of suction tubes and controllers,
Sterile suction controller,
Sterile myringotomy knife,
Sterile blunt needle grommet inserter,
Sterile tympanostomy tubes both rigid and soft,
Sterile septal nasal splint.

Annex V (sterility aspects only)
Myringotomy kits,
Sterile ear curettes,
Sterile ear speculae.

This certificate is valid from 23 December 2004 until 23 December 2008
Issue 1. Certified since 23 December 2004

Notified Body Number 0120
Authorised by

CE
0120

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0303

SGS

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SGS

Certificate CA05/3421

The management system of
Le système de gestion de

Adept Medical Ltd.

6 McDonald Street,
Morningside, Auckland, New Zealand

has been assessed and certified as meeting the requirements of:
a été évalué et enregistré selon les exigences de la norme

ISO 13485:2003

The scope of registration is as follows:
La portée d'enregistrement est:

Design and manufacture of sterile and non sterile tympanostomy tubes both rigid and soft, ear curettes, ear specula, myringotomy knives, section tubes, suction controllers and blunt needle grommet inserters, video otoscope clip on curettes and sterile nasal splints and non sterile external nasal splints.

This certificate is valid from March 30, 2006 until March 29, 2009
Ce Certificat est valide du 30 mars, 2006 au 29 mars, 2009
Issue 2. Certified since January 2005
Édition 2. Enregistrée dupuis janvier 2005
Signed for and on behalf of SGS Systems & Services Certification Canada Inc.
Document signé pour et au nom de SGS Certification de Systèmes & Services Canada Inc.

Canadian Systems Certification Manager: William Thoms

SGS Systems & Services Certification Canada Inc.
SGS Certification de Systèmes & Services Canada Inc.
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CMDCAS Recognized Registrar.
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Page 1 of 1

SYSTEM CERTIFICATION / CERTIFICATION DE SYSTEMES / ISO 13485 / SGS

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ADEPT MEDICAL

REF: 20060608

Appendix D

Risk Analyses for Fluoroplastic Otological Ventilation Tubes

(b)(4) Trade Secret Process -Risk management Report

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Trade Secret Process -Risk management Report

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MEDICAL

REF: 20060608

Appendix E

Fluoroplastic Ventilation Tubes – Substantial Equivalence

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ADEPT MEDICAL

Fluoroplastic Ventilation Tubes – Substantial Equivalence

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 Adept Medical – NeoZoline™ Ventilation Tubes

NeoZoline™ fluoroplastic ventilation tubes are moulded from Tefzel® HT2185 Fluoropolymer Resin manufactured by DuPont (refer to Biological Safety Assessment – Ventilation Tubes). Tefzel® HT2185 is a 100% Tetrafluoroethylene-Ethylene Copolymer (refer to the Tefzel® HT-2185 Product Information Sheet).

2 Competitors' Ventilation Tubes

2.1 Atos Medical – TympoVent™

2.1.1 Contact Details

Atos Medical AB
PO Box 183, SE-242 22 Horby, Sweden
www.atosmedical.com

2.1.2 Literature / Data

- TmpoVent™ brochure, REF 7901, 200404
  Materials used - Fluoroplastic
  TympoVent ventilation tubes are also made of fluoroplastic. This material is highly regarded by otologists for its smooth texture. TympoVent tubes made of fluoroplastic are available in white or blue colour.

2.1.3 FDA

FDA 510(k) Notification Numbers:	K936275
Device Name:	TympoVent
Applicant:	Atos Medical AB
Decision Date:	05/05/1994

2.1.4 Conclusion regarding material

From the information publicly available on the Atos Medical – TympoVent™ ventilation tubes all we know is they manufacture ventilation tubes from a fluoropolymer resin (fluoroplastic).

2.2 Entermed – Aero-Tymp®

2.2.1 Contact Details

Entermed BV
PO Box 236, 3440 AE Woerden, The Netherlands
www.entermed.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2.2.2 **Literature / Data**

- Aero-Tymp® Vent Tubes brochure, July 2001
  Material
  Aero-Tymp® ventilation tubes are available in PE, FEP and silicone. These materials are held in high regard by the medical profession for their inertness and biocompatibility when used for otological implants.

- Product labels
  Product label states the material is: *PTFE*

2.2.3 **Conclusion regarding material**

From the Entermed product label we believe Entermed manufacture ventilation tubes from a PTFE (polytetrafluorethylene) fluoropolymer resin. From the Entermed brochure we believe this is probably a Teflon® FEP (fluorinated ethylene propylene resin from DuPont).

2.3 Exmoor Plastics

2.3.1 **Contact Details**

Exmoor Plastics
Lisieux Way, Taunton, Somerset, TA1 2LB, United Kingdom
www.exmoorplastics.co.uk

2.3.2 **Literature / Data**

- Exmoor Plastics Product Data catalogue, 1997 and website (Jan 2006)
  Aural Ventilation Tubes
  Materials Index: ptfe: e.g. 'Teflon'

- Product labels
  The Exmoor product labels do not state what type of material is used.

2.3.3 **FDA**

FDA 510(k) Notification Numbers:	K911580	K883667
Device Name:	Donaldson/Shepards Dr/Shah Vent-Mini Tubes	Donaldson Ventilation Tubes PT.#AG/S9
Applicant:	Exmoor Plastics Ltd	Exmoor Plastics Ltd
Decision Date:	08/24/1991	11/14/1988

FDA 510(k) Notification Numbers:	K812460	K810701
Device Name:	Various Aural Grommets	Exmoor Aural Grommet
Applicant:	Exmoor Plastics Ltd	Exmoor Plastics Ltd
Decision Date:	09/21/1981	01/14/1981

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2.3.4 Conclusion regarding material

From the information publicly available on the Exmoor ventilation tubes we know they manufacture ventilation tubes from a PTFE (polytetrafluorethylene) polymer (probably a Teflon® from DuPont).

2.4 Gyrus ENT

2.4.1 Contact Details

Gyrus ENT
410 Wharfdale Rd, Winnersh Triangle, Wokingham, Berks RG41 5RA, UK
www.gyrus-ent.com

2.4.2 Literature / Data

- "First in Myringotomy" brochure, REF 7060-0977, 4/03
  Material: Fluoroplastic

- Instruction Sheet – 4434505 Rev 09/02
  Many styles of ventilation tubes are available with various material options. These materials include Fluoroplastic, Silicone, Stainless Steel, Titanium and Polyethylene.

- Product labels
  The Gyrus product labels state the material is: *Fluoroplastic*

2.4.3 FDA

FDA 510(k) Notification Numbers:	K992222	K000801
Device Name:	Fluoroplastic Ventilation Tubes	PC Coated Fluoroplastic Vent Tubes
Applicant:	Gyrus ENT LLC	Gyrus ENT LLC
Decision Date:	08/26/1999	06/19/2000
Material:	*Fluoroplastic meeting ASTM F754*	*Fluoroplastic meeting ASTM F754*

ASTM F 754 – Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube, and Rod Shapes

This specification describes the performance of polytetrafluoroethylene (PTFE) fabricated in sheet, tube, and rod shapes which may be used for surgical implants. PTFE is a member of the generic class of perfluorocarbon (containing only the elements fluorine and carbon) polymers.

Perfluorocarbon high polymers are solids exhibiting extraordinary thermal and chemical stability. They do not require stabilizing additives of any kind.

The biological response to PTFE in soft tissue and bone has been well characterized by a history of clinical use and animal studies (1-9).

This specification does not apply to specific surgical implants. Such implants would be subject to appropriate end-use performance standards.

This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2.4.4 **Conclusion regarding material**

From the information publicly available on the Gyrus ventilation tubes all we know is they manufacture ventilation tubes from a fluoropolymer resin (fluoroplastic). Gyrus also states that their fluoroplastic material meets the ASTM F754 standard which relates to PTFE (polytetrafluorethylene), we can therefore assume they manufacture ventilation tubes from a PTFE (polytetrafluorethylene) polymer (possibly a Teflon® from DuPont).

2.5 Medtronic Xomed

2.5.1 **Contact Details**

Medtronic Xomed Inc
6743 Southpoint Drive, North, Jacksonville, FL 32166, USA
www.xomed.com

2.5.2 **Literature / Data**

- Website – Jan 2006
  Material: FLPL: Fluoroplastic

- Xomed Catalogue Poster, 1972
  Material: Teflon – Registered Trademark of E.I. DuPont

- Product labels
  The Medtronic Xomed product labels state the material is: *Fluoroplastic*

2.5.3 **FDA**

FDA 510(k) Notification Numbers:	K941407
Device Name:	Tympanostomy (Ventilation) Tube
Applicant:	Xomed-Treace Inc
Decision Date:	03/14/1995

2.5.4 **Conclusion regarding material**

From the information publicly available on the Gyrus ventilation tubes we know they manufacture ventilation tubes from Teflon which is a PTFE (polytetrafluorethylene) polymer (probably a Teflon® PTFE from DuPont).

2.6 Micromedics Inc

2.6.1 **Contact Details**

Micromedics Inc
1285 Corporate Center Drive, Eagan, Minnesota 55121, USA
www.micromedics-usa.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2.6.2 **Literature / Data**

- Micromedics Ventilation Tubes catalogue, REF MK-0148A, 2002

  Designs and Materials

  Micromedics tympanostomy tubes are available in a wide variety of designs and materials to meet nearly any surgical requirement. Each design description includes the tubes' material and color. Micromedics vent tubes are constructed of materials that have been fully tested for biocompatibility.

  Fluoroplastic is inert, biocompatible, and very smooth. The rigid material facilitates tube insertion and its non-stick charachteristics may reduce adhesion formation and/or clogging. Teflon (a registered trademark of E.I. DuPont de Nemours & Co.) is one brand of fluoroplastic. Micromedics uses only 100% Certified Virgin Material, certified in accordance with ASTM D1710-81 Type 1, Grade 1.

  ASTM 1710 – Standard Specification for Extruded and Compression Molded Polytetrafluorocthylene Rod and Heavy-Walled Tubing

- Instruction Sheet – 20010 RevD

  Implants are manufactured with a variety of materials such as silicone elastomer, fluoroplastic, stainless steel or titanium.

2.6.3 **FDA**

FDA 510(k) Notification Numbers:	K830228
Device Name:	Otological Ventilation Tubes – Various
Applicant:	Micromedics Inc
Decision Date:	03/07/1983

2.6.4 **Conclusion regarding material**

From the information publicly available on the Micromedics ventilation tubes we know is they manufacture ventilation tubes from a PTFE (polytetrafluorethylene) polymer (probably a Teflon® from DuPont).

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3 Fluoroplastics (Fluoropolymer Resins)

3.1 What is a Fluoroplastic or Fluoropolymer?

A group of plastics where the molecules contain carbon and fluorine which dramatically change the properties to include: very high working temperatures, no-stick characteristics, very high resistance to chemicals and solvents, and very high electrical resistance.

F ***fluorine*** Fluorine typically imparts chemical resistance, thermal stability, and low surface energy. Fluoro Intermediates are used as the key building blocks required to produce fluoropolymers.

TFE ***tetrafluoroethylene*** TFE is the key per fluorinated monomer used to produce a wide range of fluoropolymers. Most fluoropolymer products are derived from TFE. This monomer can also be used to add fluorinated functionality to a variety of hydrocarbon precursors. For example, a fluorinated ether can be synthesized through nucleophilic addition of an alkoxide across the double bond of TFE.

PPVE ***perfluoropropyl vinyl ether*** A clear liquid that is useful as a comonomer in polymerizations and can also be used to add fluorinated functionality to organic precursors. PPVE is a per fluorinated vinyl ether comonomer that is used in polymerizations to produce fluoroplastics. Per fluorinated vinyl ethers are effective in disrupting crystallinity in TFE based polymers and PPVE is commonly used in the synthesis of PFA. Two co-polymers using PPVE as co-monomer are commercially important: TFM, a copolymer with about 0.1% PPVE & PFA, a copolymer with 3-15% PPVE.

PTFE ***polytetrafluoroethylene*** Basic PTFE is a linear polymer of TFE and is a true homopolymer. Virgin (pure) PTFE is the most unusual and exhibits the best performance in terms of temperature resistance, chemical resistance, and non-stick properties. Its major disadvantage is that it does not actually melt when heated and therefore is difficult to process, and very unconventional techniques are needed to mold, extrude and weld it.

Modified PTFE ***polytetrafluoroethylene*** Modified PTFE is skived from a modified homopolymer PTFE resin containing some percentage of a fully fluorinated comonomer (usually PPVE). This chemically modified version of PTFE yields a material with improved electrical and physical properties over virgin PTFE. The result is a material that exhibits equivalent chemical resistance, increased tensile strength and greater elongation. Unlike virgin PTFE, conventional plastic techniques can be used to process this material (ie thermally bonding or fusing Modified PTFE to itself). Because of these properties

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Modified PTFE is often a lower cost alternative to other melt processable films (ie PFA and FEP).

FEP ***fluoroethylene-propylene*** FEP was developed by DuPont as a Melt Processable fluoropolymer which can be processed by normal plastic methods unlike virgin PTFE. With the same benefits as other fluoropolymers FEP has a lower maximum operating temperature.

PFA ***perfluoralkoxy*** PFA was developed by DuPont as a High Temperature fluoropolymer with a maximum operation temperature of 500?F (260?C), while maintaining similar properties to other fluoropolymers. Of course this added temperature resistance also adds a significant increase in cost. PFA is a melt-processable thermoplastic with similar chemical resistance to PTFE, but has much lower porosity and is translucent.

ETFE ***ethylene-tetrafluoroethylene-copolymer*** ETFE was developed by DuPont as a Tough fluoropolymer with similar hardness compared to nylon, unlike virgin PTFE & FEP. The improvements in stiffness is paid for by reduced chemical resistance and working temperature.

3.2 History of Fluoroplastic

PTFE or polytetrafluoroethylene was discovered on April 6, 1938 by Dr. Roy Plunkett at the DuPont research laboratories (Jackson Laboratory in New Jersey). Plunkett was working with gases related to Freon® refrigerants when upon checking a frozen, compressed sample of tetrafluoroethylene, he and his associates discovered that the sample had polymerized spontaneously into a white, waxy solid to form polytetrafluoroethylene or PTFE.

PTFE was first marketed under the DuPont Teflon ® trademark in 1945. The molecular weight of Teflon can exceed 30,000,000, making it one of the largest molecules known. The surface is so slippery, virtually nothing sticks to it or is absorbed by it

3.3 Fluoroplastic Manufacturers

There are a number of manufacturers of fluoropolymer resins including Dupont®, Dyneon™, Saint-Gobain Norton®, and Norton® amongst others. Due to their history Dupont® is the best know manufacturer of fluoropolymers. Dupont® and Teflon® have become a familiar household names, recognized worldwide for the superior non-stick properties associated with its use as a coating on cookware and as a soil and stain repellant for fabrics and textile products.

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3.4 Dupont® Fluoroplastics

The family of Teflon® fluoropolymers from DuPont include:

- Teflon® PTFE, the original resin
- Teflon® FEP, introduced in 1960
- Tefzel® ETFE in 1970
- Teflon® PFA, in 1972.

Each of these fluoropolymer types are available in a dozens of different grades which are normally selected depending on the end product being made and its processing conditions.

According to Dupont technical information Melt-Processible Fluoroplastics suitable for injection molding small specialty parts (such as ventilation tubes) include:
Tefzel® ETFE Fluoropolymer Resin
Teflon® FEP Fluoropolymer Resin
Teflon® PFA Fluoropolymer Resin

Subsequently Tefzel® HT-2185 has been selected for the use of injection moulding the NeoZoline™ ventilation tubes.

4 Conclusion

From this study we know our competitors use fluoropolymer resins to manufacture ventilation tubes. We do not however know what exact type of fluoroplastic is used by our competitors and unless the details of the fluoroplastic manufacturer, type, name and grade were obtained (which is unlikely due to the proprietary nature of this information) it is impossible to prove exact substantial equivalence of material. It is important to note that there are a variety of different fluoroplastics and the terms Teflon®, PTFE, ETFE and Fluoroplastic are used interchangeably.

We suspect most of our competitors (including Medtronic Xomed and Gyrus ENT) use a Teflon® from DuPont, possibly a Teflon® PTFE. We also believe that Entermed manufacture their ventilation tubes from Teflon® FEP.

However without having access to the proprietary information of our competitors it is impossible to identify exactly which fluoroplastic (type and grade) they have used. From our detailed knowledge of fluoropolymers (Adept has manufactured plastic injection mouldings for over 30 years) we consider the chemical structure of all fluoroplastics (the molecules contain carbon and fluorine) used to manufacture ventilation tubes to be substantially equivalent regardless of whether they are referred to as Teflon®, PTFE, ETFE or FEP.

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