



# U.S. Department of Health & Human Services

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## Food and Drug Administration

### SAVE REQUEST

**USER:** (jmr)  
**FOLDER:** K030605 - 113 pages  
**COMPANY:** ZYGOMATICS LTD. (ZYGOMATICS)  
**PRODUCT:** LOCK, WIRE, AND LIGATURE, INTRAORAL (DYX)  
**SUMMARY:** Product: RAPID IMF

**DATE REQUESTED:** Oct 2, 2015

**DATE PRINTED:** Oct 2, 2015

**Note:** Printed





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUN 27 2003**

Ms. Carol MacDonald  
QA/RA Manager  
Zygomatics, Limited  
20A Montpelier Vale  
London SE3 OTA,  
UNITED KINGDOM

Re: K030605

Trade/Device Name: RAPID IMF™  
Regulation Number: 21 CFR 872.4600  
Regulation Name: Intraoral Ligature and Lock Wire  
Regulatory Class: II  
Product Code: DYX  
Dated: May 11, 2003  
Received: May 16, 2003

Dear Ms. MacDonald:

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.

Page 2 – Ms. MacDonald

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.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Susan Runner, DDS, MA  
Interim Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: ZYGOMATICS LTD

510(k) Number (if known): K030605

Device Name: RAPID IMF™

Indications For Use:

The Rapid IMF is an adjustable flexible plastic band that wraps around a tooth to create an anchorage point for maxillo-mandibular fixation and immobilisation (similar to an orthodontic band). Rapid IMF is suitable for:

- Pre-operative fixation
- Per-operative fixation
- Short-term (up to 3 weeks) fixation for minimally displaced fractures
- Splintage post jaw dislocation

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

*Karin Moley SA MDR*  
K030605

(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

Date: 1/6/05

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K030605/A'

To: Division Director: DE/DAGID

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

\_\_\_\_\_ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

\_\_\_\_\_ Additional information requires a new 510(k); however, the information submitted is incomplete. (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

\_\_\_\_\_ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

**CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)**

\_\_\_\_\_ Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

\_\_\_\_\_ Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

\_\_\_\_\_ No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: RSB [Signature] 1/28/05

Date: \_\_\_\_\_

Draft #2 : 9/8/99  
Draft #3: 1/3/00  
Draft #4: 3/7/03

DMC  
2/2



ZYGOMATICS

Zygomatix Ltd  
7 Laggary Park  
Rhu  
G84 8LY  
Scotland

phone 44 (0)1436 821896  
fax 44 (0)1436 821897  
info@zygomatix.net

December 22, 2004

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

FDA/CDRH/OCE/PMD  
7/13/03  
P 2:00

Dear Sir Madam:

I would like to transfer premarket notification, K030605, RAPID IMF to Synthes (USA), 1690 Russell Road, Paoli, 19301.

Ref: DEVICE: RAPID IMF  
ZYGOMATICS LTD.                    510(k) NO: K030605 (TRADITIONAL)  
ATTN: CAROL MACDONALD            PHONE NO : 440 780 1655887  
20A MONTPELIER VALE                SE DECISION MADE: 27-JUN-03  
LONDON SE3 0TA, UNITED KINGDOM   510(k) STATEMENT

Yours sincerely,

Duncan F Campbell FRCS, FDS, MB BS, BDS  
CEO, Zygomatix Ltd

SK29  
2



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JAN 28 2005**

Zygomatix, Ltd.  
Duncan F. Campbell  
CEO  
7 Laggary Park, Rhu  
G84 8LY  
Scotland

Re: k030605 – Rapid IMF

Dear Mr. Campbell:

We have reviewed your letter, dated December 22, 2004, stating that the rights to the above referenced premarket notification (510(k)) have been transferred. Transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.81(a)(3). Consequently, we cannot change the name of the original 510(k) submitter in our database. We suggest that information showing the transfer of the 510(k) and its current ownership should be maintained in the company's files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (240) 276-0100 if you have any questions on what information we expect to be maintained in your files.

If you have any other questions regarding this letter, please contact the 510(k) Staff at (301) 594-1190.

Sincerely yours,

Heather S. Rosecrans  
Director, Premarket Notification Section  
Program Operations Staff  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

cc: Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301

Zygomatix, Ltd.  
Fasgadh Dunivard Rd.  
Garelochhead  
Scotland G84 0AP  
UK

Zygomatix, Ltd.  
20A Montpelier Vale  
London SE3 0TA  
UK

3



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 28 2005

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Duncan F. Campbell  
CEO  
7 Laggary Park, Rhu  
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Director, Premarket Notification Section  
Program Operations Staff  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

cc: Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301

Zygomatics, Ltd.  
Fasgadh Dunivard Rd.  
Garelochhead  
Scotland G84 0AP  
UK

Zygomatics, Ltd.  
20A Montpelier Vale  
London SE3 0TA  
UK

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

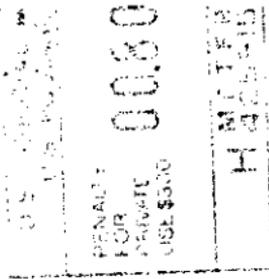
Public Health Service  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

WF2-404

Official Business

Penalty for Private Use \$300

RETURN TO SENDER



NO LONGER AT THIS ADDRESS

Zygomatix, Ltd.

Fasgadh Dunivard Rd.

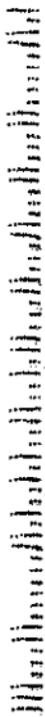
Garelochhead

Scotland G84 0AP

UK

AIR MAIL

00144/8000





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUN 27 2003**

Ms. Carol MacDonald  
QA/RA Manager  
Zygomatics, Limited  
20A Montpelier Vale  
London SE3 OTA,  
UNITED KINGDOM

Re: K030605

Trade/Device Name: RAPID IMF™  
Regulation Number: 21 CFR 872.4600  
Regulation Name: Intraoral Ligature and Lock Wire  
Regulatory Class: II  
Product Code: DYX  
Dated: May 11, 2003  
Received: May 16, 2003

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Page 2 – Ms. MacDonald

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Sincerely yours,



Susan Runner, DDS, MA  
Interim Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: ZYGOMATICS LTD

510(k) Number (if known): K030605

Device Name: RAPID IMF™

Indications For Use:

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- Per-operative fixation
- Short-term (up to 3 weeks) fixation for minimally displaced fractures
- Splintage post jaw dislocation

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

*Kevin Maly SA MSR*  
K030605

(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: \_\_\_\_\_

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 24, 2003

ZYGOMATICS LTD.  
20A MONTPELIER VALE  
LONDON SE3 0TA,  
UNITED KINGDOM  
ATTN: CAROL MACDONALD

510(k) Number: K030605  
Product: RAPID IMF

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The deficiencies identified 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>

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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

February 25, 2003

ZYGOMATICS LTD.  
20A MONTPELIER VALE  
LONDON SE3 OTA,  
UNITED KINGDOM  
ATTN: CAROL MACDONALD

510(k) Number: K030605  
Received: 25-FEB-2003  
Product: RAPID IMF

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

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

48

Dear Document Centre Executive

I must apologise for these documents *not being hole-punched*, however, as we do not have a US 3-hole punch, I thought it would cause more problems when you re-bind these documents if we had approximated the spacing with a UK punch.

Once again, please do accept my apologies.

Yours sincerely

Carol MacDonald

FDA/CDRH/OCE/DID  
2003 FEB 25 P 12:37

SK-32

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DE  
F

FDA (CDRH/OCE/DID)

2003 FEB 25 P 12:38

**Zygomatix Ltd**  
**C/O 20A Montpelier Vale**  
**London SE3 0TA**



ZYGOMATICS

**PREMARKET NOTIFICATION [510(k)] SUBMISSION**

*Date of Submission:* 11<sup>th</sup> February 2003

Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850 USA

Dear Madam/Sir:

**510(K) NOTIFICATION**

Zygomatix Ltd. hereby submits this **510(k) Notification** for consideration for substantial equivalence for the Zygomatix Rapid IMF™ Temporary Mandibular Fixation Device. Devices of this type have previously been reviewed by the Dental Division of the Office of Device Evaluation.

The **contact person** is Ms Carol MacDonald, Zygomatix Regulatory & Quality Director and Official Correspondent. **Please send all correspondence regarding this submission to:**

Ms Carol MacDonald  
ZYGOMATICS LTD  
Regulatory & Quality Director  
20A Montpelier Vale  
London SE3 0TA  
UK

phone 44 (0)7801 655 887  
Email: [macdcr1@aol.com](mailto:macdcr1@aol.com)

The applicant manufacturer's registered address and contact details for your records are as follows:

ZYGOMATICS LTD  
"Fasgadh"  
Dunivard Road  
Garelochhead  
G84 0AP  
Scotland  
U.K.

phone 44 (0)1436 810801  
fax 44 (0)1436 811442  
[info@zygomatix.net](mailto:info@zygomatix.net)

The addresses of the manufacturing & sterilization sites are as follows:

(Injection Moulding sub-contractor)  
rk  
(b) (4)

(Packaging sub-contractor)

(b) (4)

(Sterilisation sub-contractor)

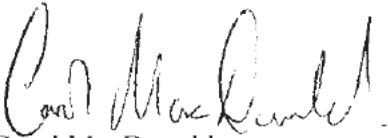
(b) (4)

We ask that this notification be treated as confidential in accordance with the Freedom of Information Act, CFR 21 20.116.

Based on the information provided, we believe the Zygomatics Rapid IMF™ Temporary Mandibular Fixation Device described in this submission is substantially equivalent to the predicate devices.

Thank you for your consideration of our application. If you have any questions regarding this notification, please do not hesitate to contact me.

Yours sincerely

  
Carol MacDonald  
Regulatory and Quality Director

Confidential

**ZYGOMATICS LTD.**  
**510(k); Premarket Notification**  
For the Rapid IMF™ Temporary Mandibular Fixation Device

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8.0 Comparison with Cleared Device	7
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**ATTACHMENTS:**

- Attachment 1 Truthful and Accurate Statement •
- Attachment 2 Tensile Strength Test Report IMF Device
- Attachment 3 Material Information
- Attachment 4 Biocompatibility Test Reports
- Attachment 5 Bioburden Reports
- Attachment 6 Ethylene Oxide Residuals Report
- Attachment 7 Intended Use Statement
- Attachment 8 Labelling & Instructions for Use
- Attachment 9 Elastic Chain Product Information
- Attachment 10 510(k) Statement •

Confidential

## **Zygomatrics Ltd. 510(k): Premarket Notification**

### **1.0 TRUTHFUL AND ACCURATE STATEMENT**

The truthful and accurate statement is at Attachment 1.

### **2.0. DEVICE NAME**

**Trade Name:** Rapid IMF™

**Classification Name:** Orthodontic appliance and accessories

### **3.0. ESTABLISHMENT ADDRESS AND REGISTRATION**

The address of the product manufacturer is:

Zygomatrics Ltd  
Fasgadh  
Dunivard Road  
Garelochhead  
G84 0AP  
Scotland  
UK

In accordance with 21 CFR 807.87, Zygomatrics Ltd. will file the required establishment registration documentation within 30 days of marketing the device.

### **4.0. DEVICE CLASSIFICATION**

Devices of this type have been classified as **Class I**, product code DYO under 21 CFR 872.5410.

### **5.0. PREDICATE DEVICE INFORMATION**

- a) Dentaurum Steel Ligature Wires, 510(k) number K935140, manufactured by Dentaurum Inc., regulation number 872.5410.

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- b) Stainless Steel Orthodontic Products, 510(k) number K931980, manufactured by Ortho Organizers Inc., regulation number 872.5410.

Section 6.0 below provides the new device description and Section 8.0 the comparison to the predicate device.

## **6.0. DEVICE DESCRIPTION & PERFORMANCE**

### **6.1. Clinical Use**

The facial bones, particularly those in the mouth are commonly subject to trauma either due to vehicle accidents or assault. As is well known, inter maxillary fixation is commonly required in the treatment of facial fractures and orthognathic surgery. The restoration of bony continuity is dependent upon accurate foundations for repositioning the fractured segments. Similarly surgery for facial deformity involves repositioning of surgically divided facial bones and requires similar fixed foundation points. These foundation points then form the base to which smaller fragments can be fixed with 'meccano like' plating systems. These foundation points are termed anchorage and this anchorage may be either intra-oral, which is based upon the accurate interdigitation of the teeth, or extra-oral whereby a scaffolding like frame is placed fixed to the skull.

By far the most common method of anchorage is intra-oral, and this is commonly created by wiring the teeth together. This may be temporary, during the operation only, or for longer to allow bone healing. For many years this has been achieved by systems of wiring such as eyelets or arch bars which create multiple fixation points. Though this has given good functional results, it is time consuming to place, (around 40 minutes in experienced hands necessarily under general anaesthesia during expensive theatre time) and also presents a risk of sharps injury to the operator and the assistant. Routine oral hygiene measures are difficult while in place, and periodontal tissues are often inadvertently damaged on removal. The only function of the wire is to create hooks on the teeth such that the accurate interdigitation of the teeth can be the fixed point.

This new development intends to replace stainless steel wire in this role with a plastic oral anchorage tie device, Rapid IMF™. The product is a sterile plastic tie, similar in principle to the cable ties used to bind electrical cables (see photographs of device in the Instructions for Use at Attachment 8). It is designed to closely adhere to the tooth surface yet not damage adjacent structures or interfere with occlusion. It incorporates a hook that has ideal angulation and height with facets to allow it to be used in association with arch bars should multiple fixation points be required. The belt portion has

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been designed to be as atraumatic as possible with the locking mechanism being within the hook. The performance of the device has been validated through bench testing (tensile strength of the locking mechanism – see report at Attachment 2) and a UK MDA approved clinical investigation.

**6.2. Device Materials**

The Rapid IMF™ device is manufactured using two materials. The main body of the device is manufactured from a type of nylon, made by (b) (4) Technyl® A205F (natural). In the “Slimline” version, the tip is made from standard stainless steel (b) (4) 304, ASTM (DIN) 14301). Technical details of the nylon material are at Attachment 3.

**6.3. Biocompatibility**

As the Rapid IMF™ utilises a different material from the predicate devices (b) (4) Nylon 6.6 A205F as opposed to stainless steel), the appropriate tests were conducted to demonstrate equivalence with respect to biocompatibility.

In accordance with ISO 10993-1, the device is categorised as a “surface device” in contact with mucosal membranes, with a contact duration of category B (prolonged). In accordance with the framework guidance of ISO 10993-1 for this category of device, the following tests were performed by (b)(4) cytotoxicity, Sensitisation and Intracutaneous Reactivity. The results were as follows.

*Table 1: Summary of biocompatibility tests*

TEST	RESULT
CYTOTOXICITY	No evidence of causing cell lysis or toxicity
SENSITISATION	Test extracts showed no evidence of causing delayed dermal contact sensitization
INTRACUTANEOUS REACTIVITY	Primary Irritation Index Characterisation for the extracts was negligible

The full reports of these studies are at Attachment 4.

Confidential

## 6.4. Sterility

### 6.4.1. *Sterilization Method*

The method used for sterilisation of the Rapid IMF™ is Ethylene Oxide (EO) with devices placed in a fixed chamber.

### 6.4.2. *Validation Method*

The sterilization process for the Rapid IMF™ was validated in accordance with ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. The microbiological validation was carried out in accordance with the (b)(4) described in this standard. Pre-sterilization bioburden testing was also performed (results at Attachment 5). Physical parameter cycle validation, package integrity testing and product functionality testing were also carried out as part of the validation.

The validation confirmed the sterility assurance level (SAL) for the device to be  $10^{-6}$ .

### 6.4.3. *Product packaging*

The devices are packaged using materials recommended for use with ethylene oxide sterilisation, in an (b)(4) heat-sealed blister pack, (moulded PETG with Tyvek® lidding), then sealed in an (b)(4) blister pack (same materials), to allow aseptic presentation of the device during application. (b)(4)

### 6.4.4. *Ethylene oxide residual levels*

Testing for ethylene oxide residual levels was performed in accordance with ISO 10993- 7: 1995 Biological evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals. (b)(4)

The results for ethylene oxide and ethylene chlorhydrin residuals were well within the levels specified in ISO 10993-7 (report at Attachment 6).

Confidential

## 6.5. Device presentation

The Rapid IMF™ device has two variants, the “Standard” version which is manufactured entirely from the nylon Technyl® A205F, and the “Slimline” version, for which the curved tip section is manufactured from stainless steel (see the Instructions for Use at Attachment 8 for photographs and description of both types). The latter version was introduced as some users felt a more rigid tip helped in passing the tip through the inter-dental space.

Along with the Rapid IMF™ device, Zygomatics also supplies an elastomeric chain with each procedure pack. This natural (i.e. no colour additives) plastic chain is itself a legally marketed device in the US having cleared 510(k) review under the reference number K943420 (the applicant Jon-Ko Products Inc are the parent company of Scientific Plastics Manufacturing who manufacture the chain – see product information at Attachment 9). The chain is a Class I device under Regulation Number 872.5410. In this application the chain has the same intended use as the legally marketed device, i.e. to assist in creating intra-oral anchorage points. The chain is provided in a non-sterile form. To ensure that the ethylene oxide sterilization process did not have an adverse effect on the functionality of the chain, samples of the chain were included in the sterilization validation exercise. No adverse affects were found on the functionality (elasticity / tensile strength); results of bioburden and ethylene oxide residual testing on the chain are also included at Attachments 5 & 6.

## 7.0. INTENDED USE AND LABELING

### 7.1. *Intended Use*

The Rapid IMF intended use is:

“The Rapid IMF is an adjustable flexible plastic band that wraps around a tooth to create an anchorage point for maxillo-mandibular fixation and immobilisation (similar to an orthodontic band). Rapid IMF is suitable for:

- Pre-operative fixation
- Per-operative fixation
- Short-term (up to 3 weeks) fixation for minimally displaced fractures
- Splintage post jaw dislocation”

The Indications For Use statement can be found at Attachment 7.

Confidential

**7.2. Labelling**

The device labels (the inner and outer lids for the blister packs and the artwork for the shelf-box) and Instructions For Use are at Attachment 8.

**8.0. COMPARISON WITH CLEARED DEVICE**

*Table 2: Substantial Equivalence Comparison*

<b>CHARACTERISTICS</b>	<b>PREDICATE DEVICE</b>	<b>RAPID IMF™</b>
<b>Indications for Use</b>	To create an intra-oral anchorage point for maxillo-mandibular fixation and immobilisation	To create an intra-oral anchorage point for maxillo-mandibular fixation and immobilisation
<b>Target population</b>	Patients with jaw fracture or dislocation	Adult (greater than 15 years) patients with jaw fracture or dislocation
<b>Anatomical site</b>	Oral cavity	Oral cavity
<b>Materials</b>	Stainless steel	Nylon (Technyl) A 205F & stainless steel
<b>Performance</b>		
<ul style="list-style-type: none"> <li>▪ <b>Mechanical safety</b></li> </ul>	Similar, however sharp edged, so risk of wire damage to oral mucosa; can be painful to remove for patient	Blunt device, less potential damage to oral mucosa
<ul style="list-style-type: none"> <li>▪ <b>Human factors</b></li> </ul>	Potential glove puncture risk from cut ends of wire	Less risk of glove puncture as blunt device
<ul style="list-style-type: none"> <li>▪ <b>Biocompatibility</b></li> </ul>	Biocompatible; stainless steel very inert material and has history of clinical use	Biocompatible with respect to tests carried out
<b>Sterility</b>	Sterilised using steam by users, sterility assurance level 10 <sup>-6</sup>	Terminal sterilisation by ethylene oxide, sterility assurance level 10 <sup>-6</sup>

Confidential

### SUBSTANTIAL EQUIVALENCE

In summary, the Rapid IMF™ has the following similarities to the predicate devices which have previously received 510(k) concurrence:

- Has the same indicated use
- Use in the same anatomical site
- Uses materials of similar biocompatibility
- Has the same sterility assurance level
- Presents no greater risk to the patient or user, and
- Is as safe and effective as the predicate devices.

Therefore, in our opinion the device described in this submission is substantially equivalent to the predicate devices.

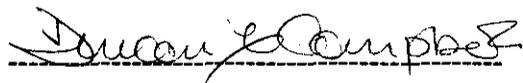
### **9.0 510(k) STATEMENT**

The 510(k) Statement is at Attachment 10.

**Attachment 1**

**TRUTHFUL AND ACCURACY STATEMENT**

Pursuant to 21 CFR 807.87(j), I, Duncan Campbell, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Managing Director of Zygomatix Ltd., and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.



*Signature*

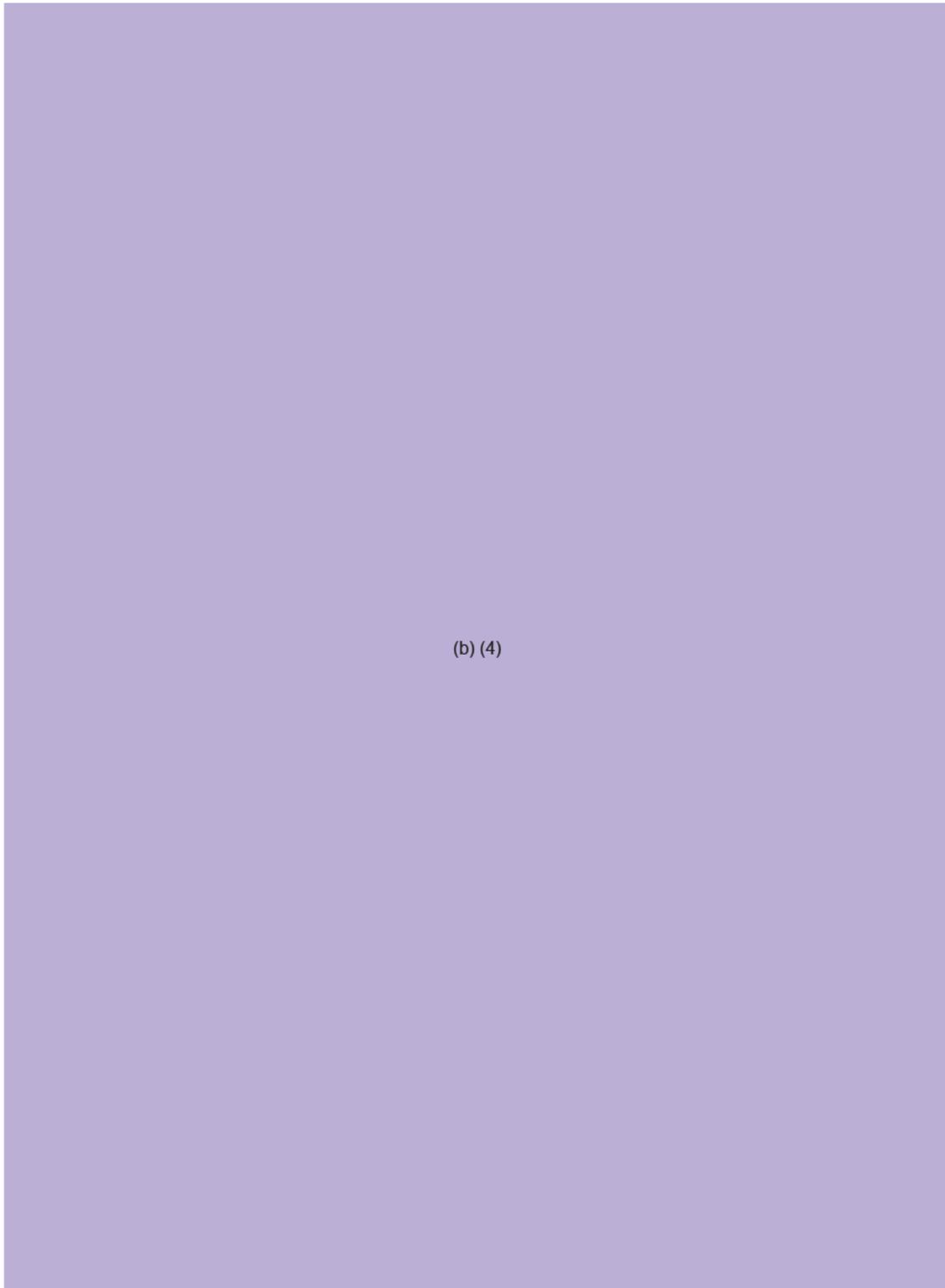
Duncan Campbell

-----  
*Typed Name*

*19th November 2002*

-----  
*Dated*

## 5-02 TEST REPORT DOCUMENT



(b) (4)

Group Confidential

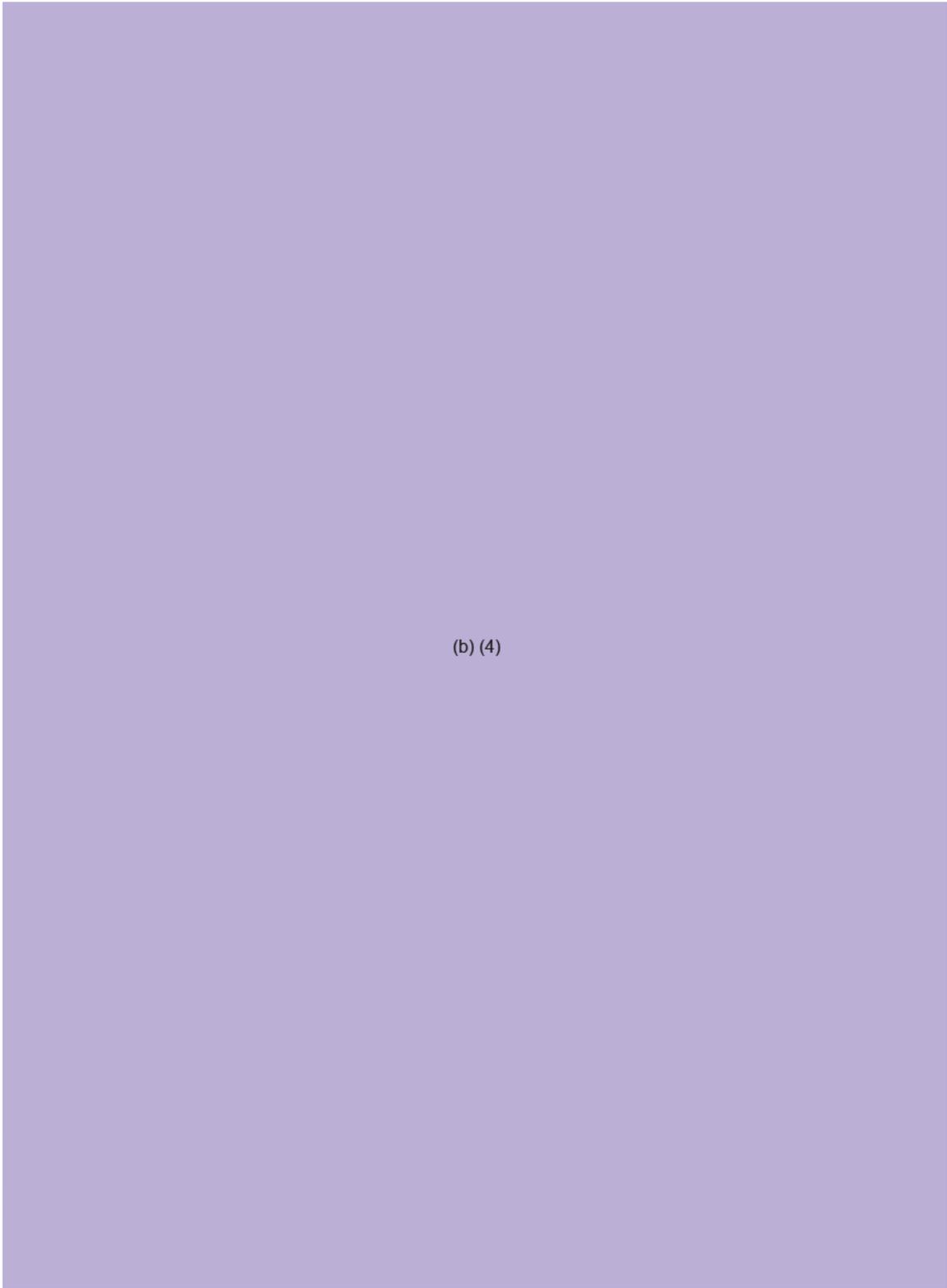
**5--02**

Issue 7

JG February 2000

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## 5-02 TEST REPORT DOCUMENT



(b) (4)

Group Confidential

**5--02**

Issue 7

JG February 2000

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@FDA.HHS.GOV or 301-796-8118

*le2*

Pages 30 through 33 redacted for the following reasons:

- (b) (4), (b) (4)  
(b) (4)-Sub-contractor material testing data

V0014-130

(b) (4)

**STUDY TITLE:**

CYTOTOXICITY STUDY USING THE ISO ELUTION METHOD

(1X MEM Extract)

(b) (4)

(b) (4)

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CONCLUSION .....	6
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TABLE	
I - REACTIVITY GRADES FOR ELUTION TESTING .....	7

SUMMARY

(b) (4)

Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The reagent control, negative control and the positive control performed as anticipated.

Study and Supervisory  
Personnel:

(b) (4)

Approved by:

(b) (4)

(b) (4)

Pages 37 through 38 redacted for the following reasons:

-----  
(b) (4), (b) (4)- testing

RESULTS

(b) (4)

CONCLUSION

Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The reagent control, negative control and the positive control performed as anticipated.

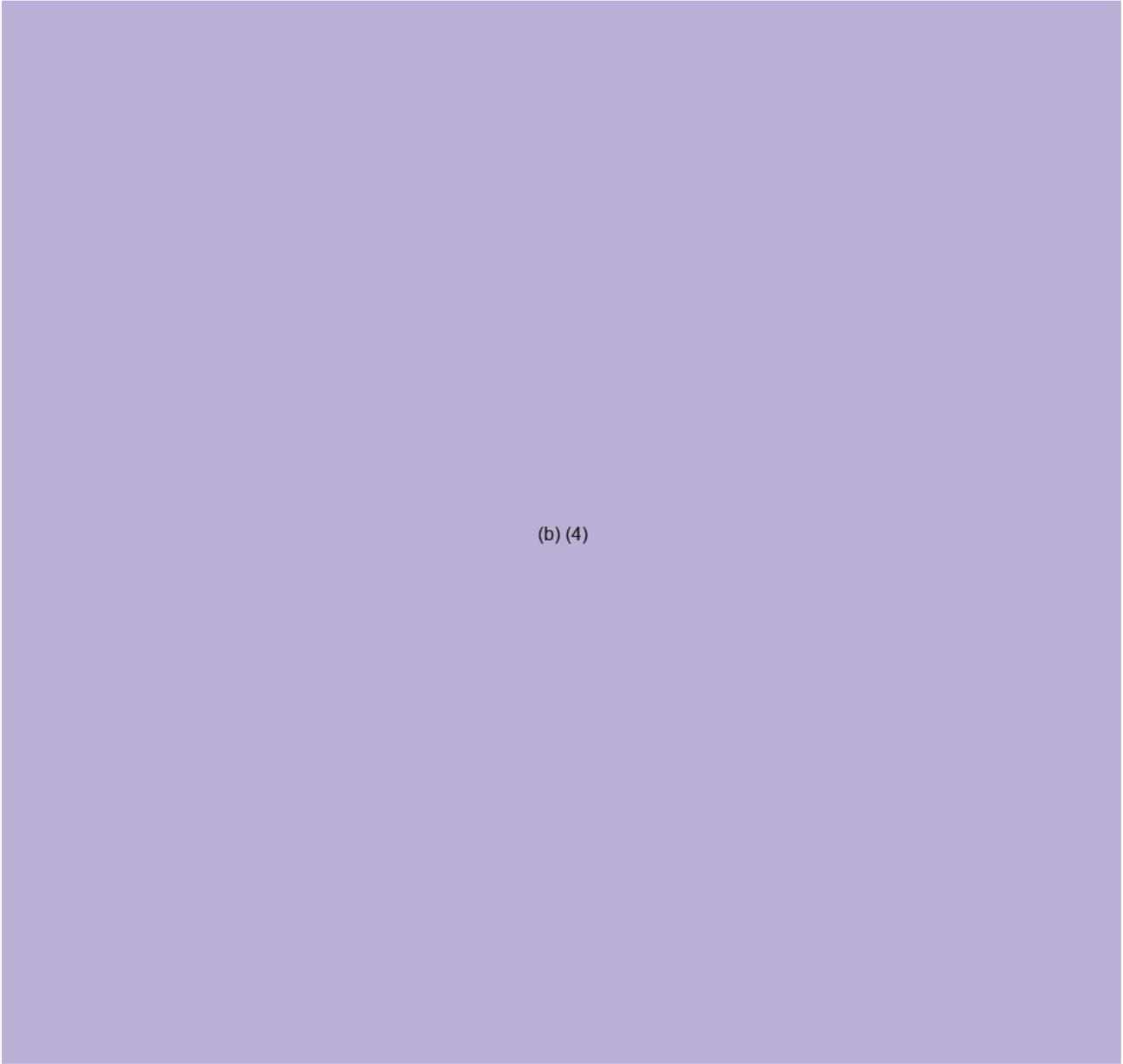
RECORD STORAGE

(b) (4)

(b) (4)

TABLE I

REACTIVITY GRADES FOR ELUTION TESTING



(b) (4)

(b) (4)

TI261-300

(b) (4)

**STUDY TITLE:**

ISO MAXIMIZATION SENSITIZATION STUDY

EXTRACT

**TEST ARTICLE:**

ZYGOMATICS RAPID IM

(b) (4)

(b) (4)

(b) (4)

TABLE OF CONTENTS

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2 - DERMAL REACTIONS - CHALLENGE .....	10

(b) (4)

SUMMARY

(b) (4)

Under the conditions of this study, the SC and CSO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

Study and Supervisory  
Personnel:

(b) (4)

Approved by:

(b) (4)

(b) (4)

Pages 44 through 46 redacted for the following reasons:

-----  
(b) (4), (b) (4)- material testing data

(b) (4)

CONCLUSION

Under the conditions of this study, the SC and CSO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

RECORD STORAGE

(b) (4)

APPENDIX I

INDIVIDUAL BODY WEIGHTS AND CLINICAL OBSERVATIONS

SC GROUP

(b) (4)

APPENDIX I (continued)

INDIVIDUAL BODY WEIGHTS AND CLINICAL OBSERVATIONS

CSO GROUP

(b) (4)

APPENDIX 2

DERMAL REACTIONS - CHALLENGE

SC GROUP

(b) (4)

APPENDIX 2 (continued)

DERMAL REACTIONS - CHALLENGE

(b) (4)

TI251-800

(b) (4)

**STUDY TITLE:**

ISO INTRACUTANEOUS STUDY

EXTRACT

**TEST ARTICLE:**

ZYGOMATICS RAPID IMF (

(b) (4)

**IDENTIFICATION NO.:**

(b) (4)

(b) (4)

TABLE OF CONTENTS

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APPENDIX	
1 - ISO INTRACUTANEOUS OBSERVATIONS.....	7

(b) (4)

SUMMARY

(b) (4)

Under the conditions of this study, there was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. The Primary Irritation Index Characterization for the extracts was negligible.

Study and Supervisory  
Personnel:

(b) (4)

Approved by:

(b) (4)

(b) (4)

Pages 55 through 56 redacted for the following reasons:

-----  
(b) (4), (b) (4)-1 testing data

(b) (4)

CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. The Primary Irritation Index Characterization for the extracts was negligible.

RECORD STORAGE

(b) (4)

Pages 58 through 65 redacted for the following reasons:

-----  
(b) (4), (b) (4)-1 testing data

Ver/ 3 - 4/24/96

Applicant: ZYGOMATICS LTD

510(k) Number (if known): K030605

Device Name: RAPID IMF™

Indications For Use:

The Rapid IMF is an adjustable flexible plastic band that wraps around a tooth to create an anchorage point for maxillo-mandibular fixation and immobilisation (similar to an orthodontic band). Rapid IMF is suitable for:

- Pre-operative fixation
- Per-operative fixation
- Short-term (up to 3 weeks) fixation for minimally displaced fractures
- Splintage post jaw dislocation

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

99

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

**Manufacturer**  
Zygomatics Ltd., Fasgadh,  
Dunivard Road,  
Garelochhead G84 0AP, UK

**Rapid IMF™**  
Temporary Mandibular Fixation Device

Contents:  
10 Fixation Devices  
1 Elastic Chain

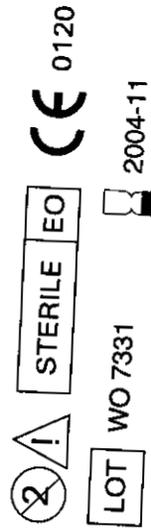


**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

**Manufacturer**  
Zygomatics Ltd., Fasgadh,  
Dunivard Road,  
Garelochhead G84 0AP, UK

**Rapid IMF™**  
Temporary Mandibular Fixation Device

Contents:  
10 Fixation Devices  
1 Elastic Chain



100

 ALEXANDER BOX COMPANY LIMITED		Customer: Zygomatics	Reference: Rapid IMF Temporary Mandibular Fixation Device 10Pack	Bar Code No: N/A	
Spec No: 6451	Print Detail: A	Inks: Cyan, Magenta, Yellow, Black, Gloss Varnish	A4 Scale: 1:2	Stretch: %	Version: 5
Cancels:	Date: 22/10/02	Screen: %	Lpi:	Artwork by: Tony Traynor	Machine:
Print Instructions:		APPROVED INK & A4 PRINT DRAWING DATE: : : SIGNED:			

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# Rapid IMF™

Temporary Mandibular Fixation Device

Simple - Safe - Effective

### Indications

- Pre-operative fracture stabilisation
- Intra-operative fracture reduction
- Short term closed reduction of simple fractures
- Prevention of TMJ re-dislocation due to muscle spasm

Visit the online clinical workshop at [www.zygomatix.net](http://www.zygomatix.net)



ZYGOMATIC'S

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 Fiskegadh  
 Dunitward Road  
 Carelochhead  
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 G43 0AP  
 Scotland

Pl: +44 (0)1436 810801  
 Fax: +44 (0)1436 811442  
 E mail: info@zygomatix.net



# Rapid IMF™

Temporary Mandibular Fixation Device

Simple - Safe - Effective



ZYGOMATIC'S

ZYGOMATIC'S CE 0120



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Placement technique for Rapid IMF ties



Choose a tooth with good contact points and angle the curved tip to pass through the distal inter dental space

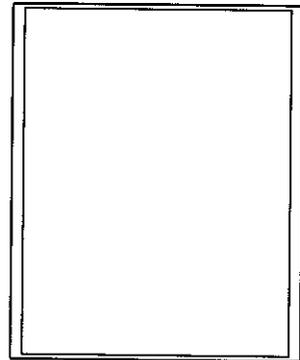


Pull the belt through maintaining apical pressure to stop the belt jamming or engaging under the contact point

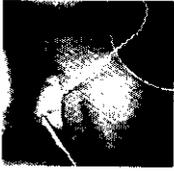


Tighten with finger pressure or with controlled traction grasping the belt with forceps. Once firm cup the belt using a scalpel or scissors.

●————●  
DISTRIBUTED BY:



Placement of Rapid IMF elastic chain



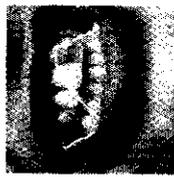
Start on an anterior maxillary anchorage point for ease of access.



Draw a link of chain over the peg until it is secure using forceps to assist.



Maintaining traction on the chain, lace the arches together in the manner shown.



Finish on an anterior maxillary tooth by again drawing a chain link over the anchorage peg and drawing it down until it is secure.

Remove any residual belt.

FINISHED

●————●  
**IMPORTANT - ALWAYS CHECK AND ADJUST THE CHAIN TENSION AT REVIEW DAYS 1,3,5,7,14, 21**



●————●  
Removal technique

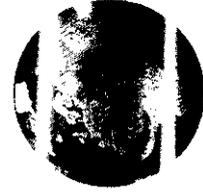
Lever the tooth away from the arch and cut the belt at the dark weak point on the belt, which is near the origin of the belt from the main body of the device.

Ease free with forceps

**RapidIMF™**

Temporary Mandibular  
Fixation Device

Instructions for use



ZYGOMATICS

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**INTENDED USE**

The Rapid IMF is an adjustable flexible plastic band that wraps around a tooth to create an anchorage point for maxillo-mandibular fixation and immobilisation similar to an orthodontic band. Rapid IMF is suitable for:

- Pre operative fixation
- Per operative fixation
- Short term fixation (up to 3 weeks) for minimally displaced fractures
- Splintage post TMJ relocation

**Good practice**

- Assess which teeth will serve for anchorage by viewing the pre operative x ray
- At least 6 anchorage points are required but 4 in each arch is preferred
- Choose teeth which are not overly crowded and which have contact points on both sides
- Do not use lower incisors if closed reduction is intended.
- Tighten the ties to finger tight; similarly the elastic loading requires only to be firm.

**FOR OPEN REDUCTION REMOVE THE TIES AT THE END OF THE PROCEDURE**

**FOR CLOSED REDUCTION THE TIES MUST ALWAYS BE LOADED BY ELASTIC TENSION TO AVOID MUCOSAL PRESSURE ULCERATION**

TRANSFER THE PATIENT TO A SOFT DIET AS SOON AS POSSIBLE

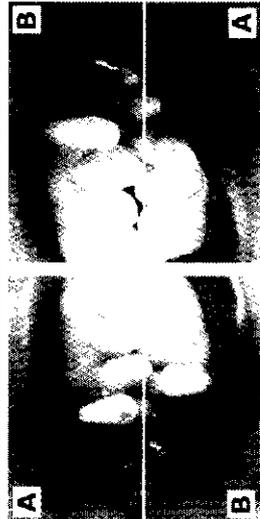
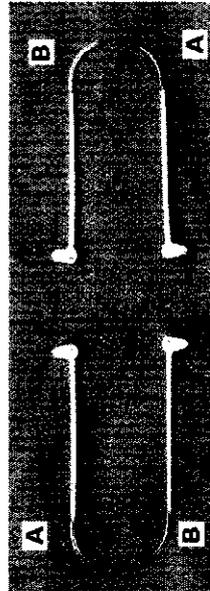
**standard** - *minimally traumatic due to flexible tip*



**slimline** - *easier to apply due to slim rigid tip*



The ties are provided in A and B sided forms to allow the anchorage point to always be placed on the medial surface of the anchor tooth. (This is functionally more stable for closed reduction)



**Indications**

Rapid IMF is intended for fracture reduction to assist treatment of fractures of the mandible, maxilla or both when there is sufficient occlusion to guide reduction, or to stabilise mandibular joints following dislocation.

**Contraindications**

- Complex fractures
- Periodontal disease
- Dental neglect
- Orthognathic surgery
- Use in children (under 15 years)

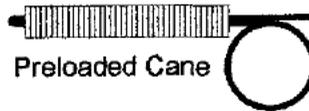
**Warnings and precautions**

- Responsibility for case selection, adequate training and choice of technique rests with the surgeon.
- The surgeon should discuss the use and expectations of the product; and post operative care with the patient.
- Importantly the product must be restricted to appropriate teeth and sufficient anchorage points used for adequate reduction and stabilisation.
- Patients must be reviewed in line with product guidelines
- Ties must be removed from any teeth with evidence or suspicion of traction-induced movement or teeth that become sensitive or painful.
- The tie belt should not be crushed by forceps as this will reduce lock strength.
- Ties should be supplemented with composite cement unless fixation is only intra operative.
- Ties must always be loaded by elastic tension to prevent mucosal pressure ulceration

**Caution:** Federal law in the USA restricts the device to sale by or on the order of a licensed healthcare practitioner.

Zygomatics Limited  
 Fasgadh, Dunivard road  
 Garelochhead, Argyll  
 G84 0AP, Scotland  
 Ph 01436 810801  
 Fax 01436 811442  
 E-mail info@zygomatics.net  
 www.zygomatics.net

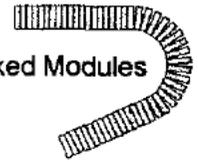
**Ligature Modules**



Preloaded Cane



Single Shot



Linked Modules

- Bulk (Individually Cut Modules Packaged Loose in a Bag, 1000 per Package) \$1.00 / Package
  - Preloaded Canes (Individual Modules Loaded onto Cane Dispensers).  
50 modules per cane, 20 canes per package. \$4.00 / Package
  - Molded Ligature Modules (Modules Molded onto Single Patient Dispensers).  
10 Modules per dispenser tab, 50 tabs per package. \$4.00 / Package
  - Linked Modules (Modules Linked Together in Continuous Tube Form). 1000 per package. \$1.75 / Package
- Colors: Gray, Clear, Black, Tooth, Light Blue, Dark Blue, Light Green, Dark Green, Pink, Purple, Red, Yellow, Orange, White, Gold, Silver, Copper

**Separator Modules**



- Radiopaque Separator Modules (Individually Cut). 1000 per package. \$3.60 / Package  
 Sizes: Small, Large • Colors: White, Blue

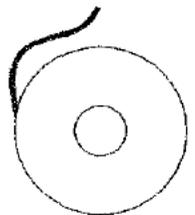
**\* Elastomeric Chain**



- Continuous Chain of Elastomeric Modules on Dispensing Spool. 8 feet per spool. \$2.50 / Spool  
 Sizes: Closed, Short, Long • Colors: Same as Ligature Modules, above.

**Sleeving and Thread/Tubing**

- Archwire Sleeving (Protective Covering for Archwires): \$0.85 / 10 Ft Spool  
 Sizes: .018 & .027 I.D. • Colors: Gray, Clear, Tooth. \$80.00 / 2000 Ft Spool
- Thread/Tubing (Solid Thread or Hollow Tubing): \$1.50 / 25 Ft Spool  
 Sizes: .025 & .030 O.D. • Colors: Gray, Clear. \$180.00 / 6000 Ft Spool



All Prices are F.O.B. San Diego, CA (USA) in US Dollars. All prices are subject to our sales confirmation.



**Scientific Plastics Manufacturing Company**

10250 Camino Santa Fe • San Diego, CA 92121-3105  
 Tel: (858) 550-0898 • Toll Free: (800) 537-9092 • Fax: (858) 550-0528  
 email: [sciplast@pacbell.net](mailto:sciplast@pacbell.net)

10/00

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**510(k) STATEMENT**  
**(As required by 21 CFR 807.93)**

I certify that, in my capacity as Regulatory & Quality Director and the Official Correspondent of Zygomatix Ltd, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification 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 patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR20.61.

.....*Carol MacDonald*.....  
(Signature of certifier)

.....Carol A MacDonald.....

.....*11<sup>th</sup> February '03*.....

.....  
(Premarket Notification [510(k)] Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Robert S. Betz DDS.  
Subject: 510(k) Number K030605/S'  
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 *COM*  
 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

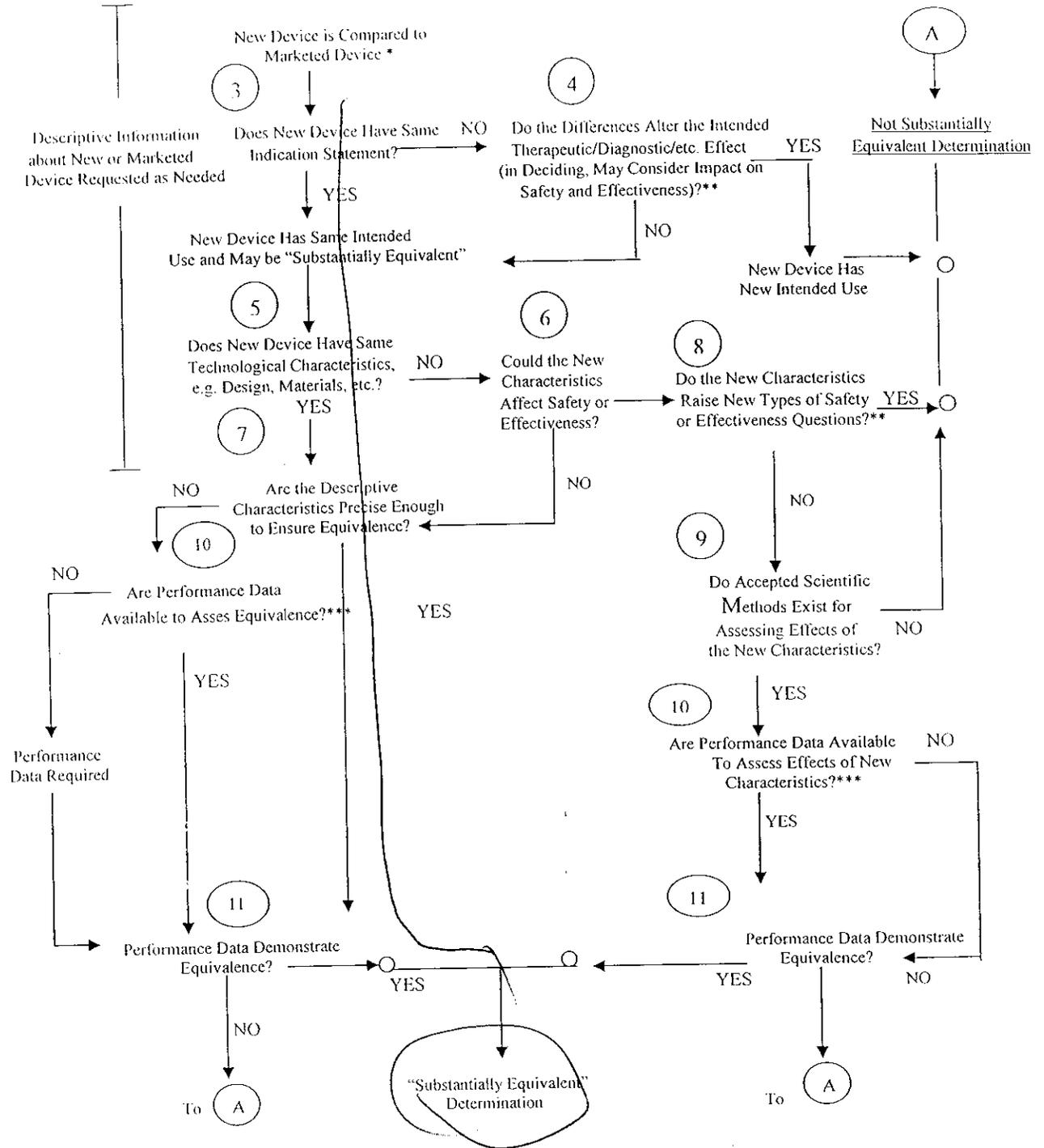
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

812.4600 CI II APX

Review: Ken Mely SA MSR DEEDB 6/26/03  
(Branch Chief) (Branch Code) (Date)

Final Review: Susan Quor 6/27/03 4  
(Division Director) (Date)

### 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.

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## INTEROFFICE MEMORANDUM

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To: The Record  
From: Robert S. Betz, DDS  
Subject: K030605/S001  
Rapid IMF  
Zygomatix Ltd.  
London, UK.

Date: 12 June, 2003

---

Recommendation: Substantially Equivalent (SE)

---

IFU: "The Rapid IMF is an adjustable, flexible plastic band that wraps around a tooth to create an anchorage point for maxillomandibular fixation and immobilization" It is suitable for per and preoperative fixation, short term fixation, and post jaw dislocation splinting.

---

The sponsor has submitted a premarket notification for their Rapid IMF device. This is described as a Class I, 76 DYO (orthodontic band) device, described in 21 CFR 872.5410. **This device should be Class II, 76 DYX device, described in 21 CFR 872.4600.** The claimed predicate device is the Dentarum Steel Ligature Wires (K935140), and Ortho Organizers Inc. orthodontic appliances described in K931980.

The Rapid IMF is described as a plastic oral anchorage tie device. The device will come in a "Standard" version, and a "Slimline" version, having a stainless steel tip to aid in passing the device through interproximal spaces. The main body of the device is made of Technyl® Nylon 6.6 A205F, which is an unreinforced polyamide nylon. The stainless steel tip in the "Slimline" version is made of (b) (4) 304 stainless steel. The sponsor claims that the stainless steel conforms to ASTM 14301.

A plastic elastomeric chain will be supplied with the device. This chain is manufactured by Scientific Plastics Manufacturing Co. has been cleared under K943420 (Jon Co Products Co.). This chain will be used for the same intended use; to assist in creating intraoral anchoring points. The target population is patients older than 15 years of age. The chain was also included in the sterilization validation procedure.

According to ISO 10993-1, the device is classified as a "surface device" in contact with mucosal membranes, and a Category B contact duration (prolonged). (b) (4) performed cytotoxicity (ISO 10993 Part5), sensitivity (ISO 10993 Part10), and intracutaneous reactivity (ISO 10993 Part10), biocompatibility testing. Reports were included under Attachment 4

6

Sterilization will be performed by ethylene oxide, and sterilization validation is claimed to be according to ISO 11135:1994, using the half cycle method described in the standard. Presterilization bioburden testing was also performed. Data was submitted in attachment 5. Physical parameter validation, package integrity testing, and product functionality testing were also carried out as a part of this validation. EtO residuals testing was performed according to ISO 10993-7:1995. A report of EtO residuals is in Attachment 6, and is claimed to be within parameters specified in ISO 10993-7. SAL is claimed to be  $10^{-6}$ .

(b) (4)

same materials, and then placed in a box. Device labeling includes the prescription warning described in 21 CFR 801.109. The instructions brochure is adequately complete for its use.

The substantial equivalence claim is based on the fact that the Rapid IMF:

1. Has the same intended use and indication for use.
2. Is used in the same anatomical site.
3. Has the same sterilization Assurance level (SAL).
4. Uses materials biocompatible like the predicate device.
5. Presents no greater risk to the patient than the claimed predicate device.

On 04-23-2003, the sponsor was sent an e-mail requesting responses to two questions:

1. I cannot find engineering drawings of your device in the submission. Please submit engineering drawings of both versions of your device.
  - a. Please include in these drawings, details of the band closure/clamping mechanism and
  - b. Please include measurement tolerances with or in these drawings.

*These drawings were submitted as requested. This response is acceptable.*

(b) (4)

- b. Please justify why you believe that the strength of your device is sufficient for its intended uses.

*The sponsor has indicated that (b) (4) if the device would result in greater than the recognized average maximum jaw opening force. When considering that it would be painful to open the mouth when either the maxilla or the mandible is fractured, there appears to be a significant margin of safety. This response is acceptable.*

Recommendation: Substantially Equivalent (SE)

This reviewer sent an E Mailed 30 day hold message 4/23/2003. They responded on 11 May, 2003. Both responses are acceptable. This device is deemed to be substantially equivalent to its claimed predicate devices. It is hereby recommended that this device be cleared for market at this time.

  
Robert S. Betz, DDS

KM  
6/26/03

REVISED:3/14/95

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

**K030605**

Reviewer: Robert S. Betz, D.D.S.

Division/Branch: DAGID/DEDB

Device Name: Rapid IMF

Product To Which Compared (510(K) Number If Known): Dentarum Steel Ligature Wires (K935140)

		YES	NO	
1.	Is Product A Device	X		If NO = Stop
2.	Is 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
10.	Performance Data Available?			If NO = Request Data
11.	Data Demonstrate Equivalence?			Final Decision: SE <i>R. S. Betz</i>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: See review.

2. Device Description: See review. Is the device life-supporting or life sustaining? No. Is the device implanted (short-term or long-term)? No. Does the device design use software? No. Is the device sterile? Yes. Is the device for single use? Yes. Is the device for home use or prescription use? Yes. Does the device contain drug or biological product as a component? No. Is this device a kit? No.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Robert S. Betz DDS.

Subject: 510(k) Number K030605

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

- Refused to accept.
- Requires additional information (other than refuse to accept). *AI - e-mail 04-23-03*
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- De Novo Classification Candidate?  YES  NO
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)
- Is this device subject to 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

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Animal Tissue Source  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 d

Predicate Product Code with class:

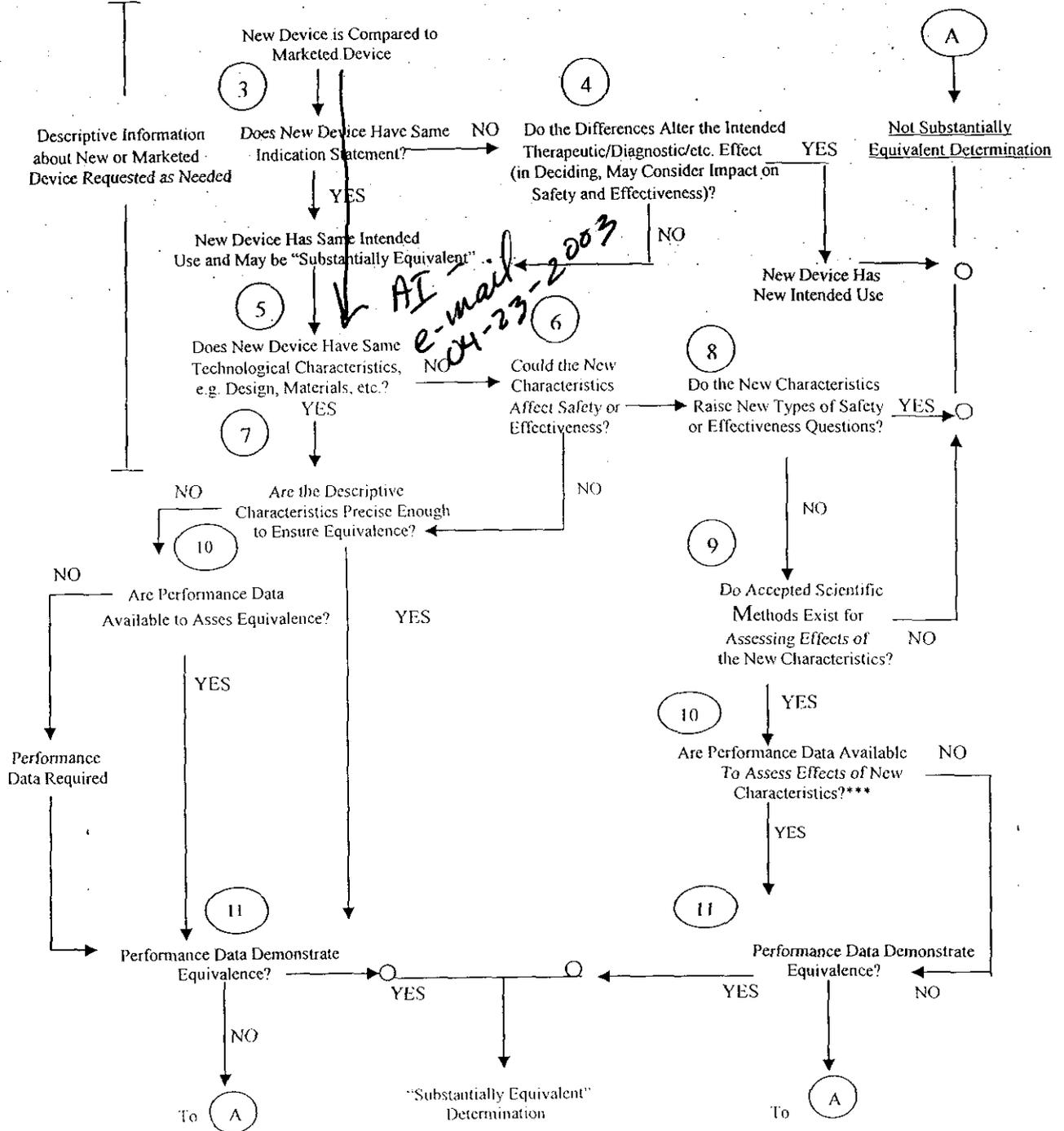
Additional Product Code(s) with panel (optional):

Review: Don Mulvey for M SR NEWSB 4/24/03  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (Date)

Revised: 8/17/99

### 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.

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## INTEROFFICE MEMORANDUM

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To: The Record  
From: Robert S. Betz, DDS  
Subject: Rapid IMF  
Zygomatix Ltd.  
London, UK.

Date: 23 April, 2003

---

**Recommendation: Additional Information Required (AI – Phone hold; E - MAIL)**

---

IFU: "The Rapid IMF is an adjustable, flexible plastic band that wraps around a tooth to create an anchorage point for maxillomandibular fixation and immobilization" It is suitable for per and preoperative fixation, short term fixation, and post jaw dislocation splinting.

---

The sponsor has submitted a premarket notification for their Rapid IMF device. This is described as a Class I, 76 DYO (orthodontic band) device, described in 21 CFR 872.5410. The claimed predicate device is the Dentarum Steel Ligature Wires (K935140), and Ortho Organizers Inc. orthodontic appliances described in K931980.

The Rapid IMF is described as a plastic oral anchorage tie device. The device will come in a "Standard" version, and a "Slimline" version, having a stainless steel tip to aid in passing the device through interproximal spaces. The main body of the device is made of Technyl® Nylon 6.6 A205F, which is an unreinforced polyamide nylon. The stainless steel tip in the "Slimline" version is made of (b) (4) 304 stainless steel. The sponsor claims that the stainless steel conforms to ASTM 14301.

A plastic elastomeric chain will be supplied with the device. This chain is manufactured by Scientific Plastics Manufacturing Co. has been cleared under K943420 (Jon Co Products Co.). This chain will be used for the same intended use; to assist in creating intraoral anchoring points. The target population is patients older than 15 years of age. The chain was also included in the sterilization validation procedure.

According to ISO 10993-1, the device is classified as a "surface device" in contact with mucosal membranes, and a Category B contact duration (prolonged). (b) (4) performed cytotoxicity (ISO 10993 Part5), sensitivity (ISO 10993 Part10), and intracutaneous reactivity (ISO 10993 Part10), biocompatibility testing. Reports were included under Attachment 4

Sterilization will be performed by ethylene oxide, and sterilization validation is claimed to be according to ISO 11135:1994, using the half cycle method described in the standard. Presterilization bioburden testing was also performed. Data was submitted in attachment 5.

Physical parameter validation, package integrity testing, and product functionality testing were also carried out as a part of this validation. EtO residuals testing was performed according to ISO 10993-7:1995. A report of EtO residuals is in Attachment 6, and is claimed to be within parameters specified in ISO 10993-7. SAL is claimed to be  $10^{-6}$ .

(b) (4)

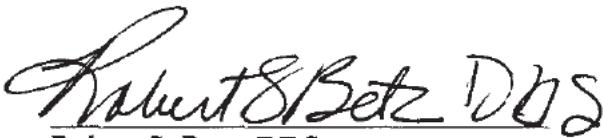
same materials, and then placed in a box. Device labeling includes the prescription warning described in 21 CFR 801.109. The instructions brochure is adequately complete for its use.

The substantial equivalence claim is based on the fact that the Rapid IMF:

1. Has the same intended use and indication for use.
2. Is used in the same anatomical site.
3. Has the same sterilization Assurance level (SAL).
4. Uses materials biocompatible like the predicate device.
5. Presents no greater risk to the patient than the claimed predicate device.

Recommendation: Additional Information Required (AI)

This reviewer sent an E Mailed 30 day hold message 4/23/2003. The text (next page) was sent to the sponsor's contact person on 23 April, 2003.

  
Robert S. Betz, DDS

KH  
4/24/03

I am the US FDA reviewer for your Premarket Notification (510(k)) submission (K030605). I have completed most of my review of your submission. There are a few items that I will need from you, to complete my review:

1. I cannot find engineering drawings of your device in the submission. Please submit engineering drawings of both versions of your device.
  - a. Please include in these drawings, details of the band closure/clamping mechanism and
  - b. Please include measurement tolerances with or in these drawings.

(b) (4)

- b. Please justify why you believe that the strength of your device is sufficient for its intended uses.

I will place this submission on telephone hold for up to 30 days so that you may have time to respond to these requests. Please respond to this e-mail so that I will know that you have received it. Please also submit hard copy of the information that I have requested to the Document Control Center where you submitted your original 510(k) submission. I will complete the review of this additional material as soon as possible after I receive this information.

If you have any questions, please feel free to e-mail or call me.

Robert S. Betz, D.D.S.  
US FDA  
(ODE/DAGID/DEDB)  
301-827-5283 Ext. 125  
[rsb@cdrh.fda.gov](mailto:rsb@cdrh.fda.gov)

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

510(k) Number: K03 0605

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.	✓	
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 in areas that are listed on page 3-4 of the Premarket Notification [510]] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
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).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

\* - 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:

	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.]		
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 <u>not</u> 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 <u>and</u> 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		
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: \_\_\_\_\_

Concurrence by Review Branch: \_\_\_\_\_

Date: FEB 26 2009

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>

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

Product To Which Compared (510(K) Number If Known): \_\_\_\_\_

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			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?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			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
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		✓
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓

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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 19, 2003

ZYGOMATICS LTD.  
20A MONTPELIER VALE  
LONDON SE3 0TA,  
UNITED KINGDOM  
ATTN: CAROL MACDONALD

510(k) Number: K030605  
Product: RAPID IMF

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

K030605/S'



Zygomatics Limited  
Fasgadh  
Dunivard Road  
Garelochhead  
Argyll  
G84 0AP  
Scotland, UK

Tel 00 44 1436 810801  
Fax 00 44 1436 811442  
E mail [info@zygomatics.net](mailto:info@zygomatics.net)

11 May 2003

Food and Drug Administration  
Center for Devices and Radiological Health  
510(k) Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

RECEIVED  
2003 MAY 16 P 2:15  
FDA/CDRH/ODE/PMO

Re: Premarket Notification (510(k)) submission (K030605)

In response in response to Dr Betz's request please find enclosed 2 copies of our response

Dear Dr Betz

Attached is our response to your emailed request 23rd April '03 for further information regarding our 510(k) submission:

- 1a) & b) The engineering drawing is attached.
- 2 a) & b) Attached is a response with clinical outcomes comparing Rapid IMF to wire.

We look forward to hearing from you regarding the outcome of our 510(k).

Best Regards

pp Carol MacDonald  
QA/RA Manager  
Zygomatics

SK 43



Zygomatix Limited  
Fasgadh  
Dunivard Road  
Garelochhead  
Argyll  
G84 0AP  
Scotland, UK  
Tel 00 44 1436 810801  
Fax 00 44 1436 811442  
E mail [info@zygomatix.net](mailto:info@zygomatix.net)

11 May 2003

Food and Drug Administration  
Center for Devices and Radiological Health  
510(k) Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

2003 MAY 16 P 2:15  
FDA/CDRH/OCE/PMO

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Best Regards

  
PP Carol MacDonald  
QA/RA Manager  
Zygomatix

## Response to examiner

With reference to 510K application for Rapid IMF

Q2a typical surgical wire gauges are 0.35mm and 0.2mm

device	(b) (4) strength (N)	(b) (4) strength (N)
(b) (4)		

Q2b

## Justification

Overview of relevant issues

1. Mandibular fractures require to be held still in the pre trauma position to
  - allow healing
  - reduce pain
  - reduce the possibility of infection
2. Physiological measurement of mandibular function
  - The healthy adult male can open his mouth against 44lbs resistance, so to immobilise and splint a mandible no more than 44lb would be required if the patient were not co-operative and insensible to pain.
  - Both wire and Rapid IMF systems exceed this requirement. In subjective assessment of healthy volunteers only 4 Rapid IMF ties were sufficient to immobilise the mandible, 8 are recommended in clinical use.

## Important points

- Mandibular fractures are very painful
- The force generated by a patient opening a fractured mandible is not known and would vary with fracture site and the patients inclination to tolerate pain
- Patient co-operation and consent is a pre requisite for treatment.
- The mandible is a not a weight bearing bone.

In summary the minimum retention required for a fractured mandible is not known and could not ethically be measured. It could not possibly be greater than 44lbs on average and is likely to be less than 4lbs, limited mainly by pain but also loss of muscle attachment to the tooth bearing segment.

## 3. Wire fixation

Wire fixation has served the test of time, and can deliver very high tensile loads in the short term but creep leads to reduction over weeks. Wire fixation with archbars is rigid initially but may require adjustment after 2-3 weeks however since patients are co-operative, the reduction in tensile load is not always noticed. It is likely that high tensile loads associated with wire loading are not symmetrical as inter arch

ligatures are multiple and adjusted by hand it seems likely that asymmetry of loading is common but not generally clinically significant.

Typically 0.2mm and 0.35mm surgical wire is used

- 0.2mm wire has a tensile strength of 19lbs (multiple ligatures will have a load equal to twice the sum of the number of ligatures (as they are looped))
- 0.35mm wire has a tensile strength of 49lbs

#### 4. Rapid IMF

(b) (4)

#### Summary

Patients with mandibular fractures do not attempt to open their mouth, as this would cause pain. The physiological requirement therefore is to immobilise the fractured segments at rest as the bone is non weight bearing.

(b) (4)

Wire has proved successful over time. Rapid IMF has proved successful in clinical trials one of which is attached showing comparison with a surgical wire technique.

Dr D F Campbell FRCS, FDS, MB BS, BDS

*Premarket Notification (510(k)) submission (K030605)*

**Rapid IMF : does it improve cross infection control in Maxillofacial Trauma surgery ?**

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Rapid IMF temporary fixation devices were provided by Zygomatics Ltd to treat the study patients.

**Background**

The treatment of maxillofacial fractures is an exposure prone procedure. During these operations the incidence of glove perforation is as high as 50% and percutaneous injuries may occur in up to 21%. The glove perforations are predominantly associated with wire penetration, holding the suture needle, and snagging gloves on arch bars. Mandibular fractures that are reduced manually while bone plated have a lower mean number of glove perforations/ operation (0.43) than fractures treated with the help of intraoperative intermaxillary fixation (IMF) such as eyelet wires and arch bars (4.62). Intraoperative use of IMF though is often needed for the reduction of certain fractures and stability during plating.

A number of IMF methods have been suggested as an alternative to the conventional wiring techniques in order to decrease the operation time and lower the risk of needle-stick injury. Rapid IMF (Zygomatics Ltd) appears to be one of the most satisfactory IMF methods studied to date. This system employs flexible plastic anchorage ties which are passed under the dental contact points. The application of intermaxillary traction is carried out with the use of elastic chain.

**Method**

(b) (4)

*Premarket Notification (510(k)) submission (K030605)*

**Results**

The results of the first stage of the study (number of patient treated: 50) show:

- A significant difference in the time required for application of Rapid IMF (mean time 12 minutes) and IMF with eyelet wires (mean time 21 minutes).
- The number of glove perforations / operation is 0.56 and 1.45 for Rapid IMF and wiring respectively.
- A reduction in the number of perforations for the assistant and theatre nurse when Rapid IMF is used.

**References**

1. Avery CME, Johnson PA: Surgical glove perforation and maxillofacial trauma: to plate or wire? Br J Oral Maxillofac Surg 1992; 30: 31.
2. Avery CME, Taylor J, Johnson PA: Double gloving and a system for identifying glove perforations in maxillofacial trauma surgery. Br J Oral Maxillofac Surg 1999; 37:316.

Pages 97 through 114 redacted for the following reasons:

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(b) (4), (b) (4)-Engineering Drawings