Biological safety assessment report

of

Orthodontics Screw

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Speed Dental Co., Ltd.

0. Revision status

No.	Revision history	Approved by	Date
0	Firstly prepared		Sep.23, 2014
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1. Introduction

This is report that confirmation biocompatibility availability of product according to connection regulation such as examination of toxicity, examination for skin stimulus and danger analysis.

The toxicity of a compound or material is investigated using basic toxicology studies which provide information on the nature of toxic effects elicited by a test material, dosages at which the effects occur and the no-effect levels. Since all chemical compounds are toxic at some level of exposure, if follows that a toxicological hazard exists for all medical devices, the material from which they are made and all ingredients, additive and processing aids associated with those material.

Where available, a summary of experience from clinical use of material should be documented. This should include detail of the nature of patient contact, the number of device used, the period of time for which they have been used and the number and nature of adverse reactions. For novel material, this information may be necessary for each ingredient.

Where the mode of patient contact or the chemical or physical nature of the established material is not identical to that in the intended application, the differences should be identified and an assessment of their significance documented. Where relevant, the results of clinical investigations which address biological safety should be included.

2. Description for Device

2.1 Product name: Orthodontics Screw

2.2 Intended use

Orthodontics screw is intended to use as a temporary anchor for orthodontic treatment

2.3 Indication use

This orthodontics screw is intended to use as a temporary anchor for orthodontic treatment. This product is intended for use only with the advice or prescription of a doctor

The orthodontics screw has the conformity to meet certain criteria falling within the applied standards. The orthodontics screw is safe and effective for user or patient with the intended use against the possible risks to user or patient.

We hereby affirm that such as the The orthodontics screw's development, verification, and validation procedures described in the risk management report have been adhered to in the design and manufacture of the orthodontics screw and that the results of test and validation procedures conducted by this company demonstrate that the system specifications and performance criteria established for this product have been fulfilled.

Orthodontics screw is intended to use as a temporary anchor for orthodontic treatment

2.4 Product description

It is an orthodontics screw, non-sterile product used as an anchor for cases which are hard to get enough anchor`s because many teeth came out, and aids from outer-mouth device for orthodontic treatments.

It is an orthodontics screw which is made of titanium alloy, and the shape of screw hole is handled as curve to lower the rate of falling off. A plate part is added to control the excessive growth of gum tissue, and the shape of screw head is simplified to prevent contamination. It resists orthodontics power by an elastic body for orthodontics, and it shall be removed after completing the role as an anchor.

2.5 Raw materials

- Titanium alloy (Titanium 6-aluminium 4-vanadium alloy) / ASTM F136

Part	Raw material				Specification	Remarks
Composition	Titanium alloy				ASTM F136 ISO 5832-3	
	N(max)	0.2	Fe(max)	0.25		
	C(max)	0.08	Al	5.5-6.5		
	H(max)	0.012	V	3.5-4.5		
	O	0.13	Ti	balance		
Physical properties	Yield Strength		115,000 psi			
	Tensile Strength		120,000 psi			
	Elongation		10 %			

3. Requirements for Standards.

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

4. Materials Analysis

4.1 Analysis of the materials contacting the Human body

This product is produced to be contacted to human body. And the main materials consisting this products is Titanium alloy (Titanium 6-aluminium 4-vanadium alloy). While using the product, the parts shown in the table below will be attached or contacted so closely. And customers may feel insecure about that. However, they do not need to feel fear because the material is very safe and non-toxic to human body. Parts contacting the human body(containing Titanium alloy (Titanium 6-aluminium 4-vanadium alloy)) have been verified of their safety by numbers of study results and literatures so far.

4.2 Material using experience

The raw materials of our products have been used in medical device field for a long time. Moreover, A great number of titanium experiments have been done at universities and industries throughout the world for the last 50 years. These experiments found the excellent biocompatibility of titanium. Moreover, this material of similar products have been used on human body for a long time, beforehand we produce this one product. There is no report and recall for the biological side effect.

4.3 Data analysis

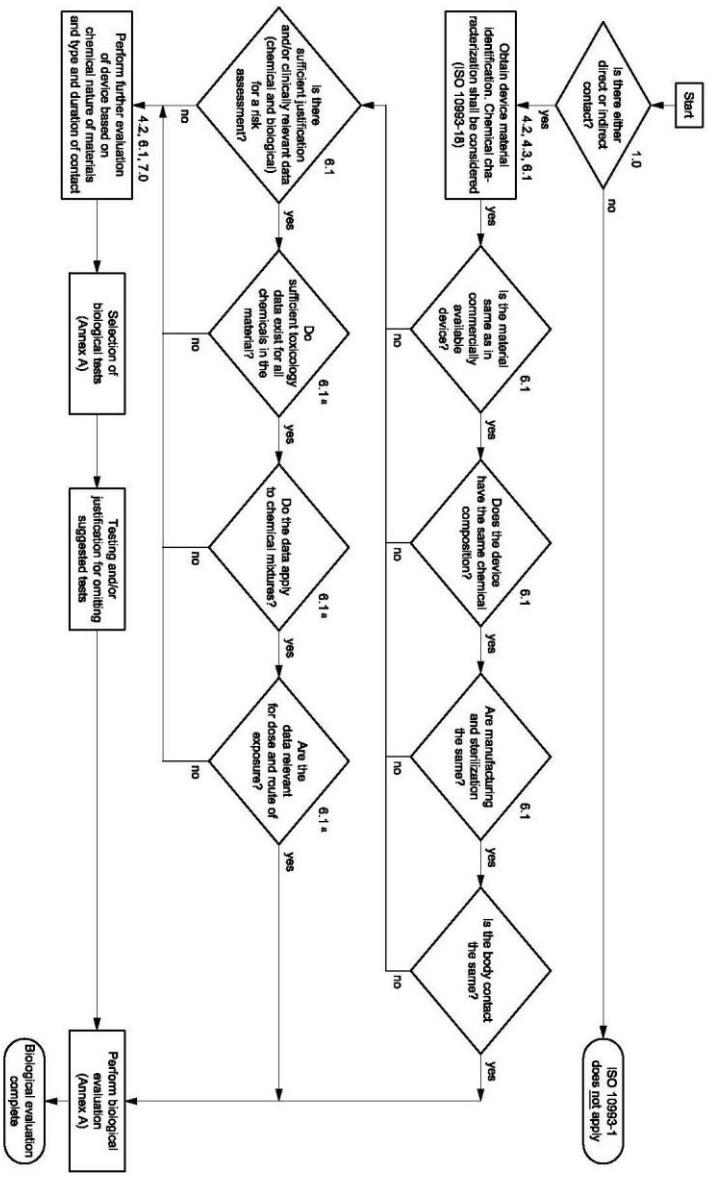
Titanium alloys based, the raw material of our products, Ti-6Al-4V, which is consisting material of the product of this company, applied the same composition as the one required by ASTM F136 and ISO 5832-3.

Ti-6Al-4V is well known of its biological safety, so that it does not need to be tested of its bio-compatibility. It is not the one that has been newly developed or the one that has not been ever used till now. It has been used in medical field for a long time.

Ti-6Al-4V, which is consisting material of the product of this company, applied the same composition as the one required by ASTM F136 and ISO 5832-3.

This material is concluded that safe enough to be used for medical devices through a toxic test in a literature. Hence, no bio-compability test was needed to be done.

[Flow Chart 1 - Summary of the systematic approach to a biological evaluation of medical devices as part of a risk management process]



[Table 1 - Evaluation tests for consideration (EN ISO10993-1:2009 Annex A)]

Medical device categorization by			Biological effect							
Nature of body contact (see 4.1)		Contact duration (see 4.2) A-Limited(24 h) B-prolonged (24h to 30day) C-Permanent (30days)	Cytotoxicity	Sensitization	Irrltation or Intracutaneous reactivity	Systemic toxicity (acute)	Subchronic toxicity (aubacuto toxicity)	Genotoxicity	Implantation	Hemocompatibility
Category	contact									
Surface	Skin	A	X[a]	X	X	·	·	·	·	·
		B	X	X	X	·	·	·	·	·
		C	X	X	X	·	·	·	·	·
	Mucosal membrane	A	X	X	X	·	·	·	·	·
		B	X	X	X	·	·	·	·	·
		C	X	X	X	·	X	X	·	·
	Breached or compromised surface	A	X	X	X	·	·	·	·	·
		B	X	X	X	·	·	·	·	·
		C	X	X	X	·	X	X	·	·
External Communicating device	Blood path, indirect	A	X	X	X	X	·	·	·	X
		B	X	X	X	X	·	·	·	X
		C	X	X	·	X	X	X	·	X
	Tissue/bone/ dentin	A	X	X	X	·	·	·	·	·
		B	X	X	X	X	X	X	X	·
		C	X	X	X	X	X	X	X	·
	Circulating blood	A	X	X	X	X	·	·	·	X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X
Implant device	**Tissue/bone**	A	X	X	X	·	·	·	·	·
		B	X	X	X	X	X	X	X	·
		C	X	X	X	X	X	X	X	·
	Blood	A	X	X	X	X	X	·	X	X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X

a The crosses indicate data endpoints that can be necessary for a biological safety evaluation, based on a risk analysis. Where existing data are adequate, additional testing is not required.

5. Conclusion

Ti-6Al-4V, which is the main source used in the product, used a material which has the same composition ratio required by ASTM F136 ISO 5832.

Based on much information and data of the materials used for this product, we have evaluated the medical conformity. Through Biocompatibility Test Report & Raw Material data, we have proven that the materials do not have any harmful effect on human body.

In conclusion, we did not perform a biocompatibility test for the materials of this product. However, these materials have been recognized to be conformable enough for customers to use this product safely without any problem onto the user's human body and do not make any harm by numbers of literatures, data, and test report.