ATHLOS
X-ray imaging technology

Athlos Oy

19/1/2022

To:

Element Materials Technology.

100 Frobisher Business Park

Malvern

Worcestershire

WR14 1BX

UK

RE: Use of SMA Connector
FCC ID: 2AX53DCDS1

To Whom It May Concern:

Please be advised that in accordance with the Bill Of Materials ("Bill of Materials-ATS_0004_Iss1.1.pdf ") we submitted (7th January 2021) to Element Materials Technology during the FCC certification filing, we do not use a reverse polarity SMA connector on this product as we meet the following criteria as set out in FCC KDB353028 D01

1) To qualify for professional installation, the applicant must explain why the hardware is not readily available to average consumer.

The medical device DC-Air™ is only imported in the USA through the Initial Importer. The authorized Initial Importer of the Athlos DC-Air™ is Freedom Technologies Group LLC ("FTG"), dully registered with the FDA for the importation and distribution in the USA of the DC-Air™ medical device. Therefore, the only avenue for the DC-Air™ medical device in the USA market is through the Athlos authorized Initial Importer. The device is not available to the average consumer.

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2) Marketing—Device cannot be sold via retail to the general public or by mail order; it must be sold to authorized dealers or installers only.

Only FTG imports and sells DC-Air™ in the USA.

FTG sells only to qualified dental professionals licensed to use x-rays. The installation is done remotely with FTG's professional installer installing the software and activating the system.

FTG also sells through FTG's authorized distributors who sell to qualified dental professionals licensed to use x-rays. The installation is done remotely with FTG's authorized dealer's professional installer(s) installing the software and activating the system or by FTG's professional installer.

3) Filing must show that intended use is not for consumers and general public; rather device is generally for industrial/commercial use.

See attached FDA formal document " Indications for Use":

"DC-Air™, Athlos-1, Athlos-Air are intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw, and oral structures."

See Athlos Instructions For Use.

4) Explain what is unique, sophisticated, complex, or specialized about the equipment that REQUIRES it to be installed by a professional installer?

This is a unique medical device which requires a specialized TWAIN bridge protocol between the dental professional's practise management system and the DC-Air™ medical device. Each and every DC-Air™ TWAIN bridge protocol is activated for use by FTG's professional installer or by FTG's authorized dealer's professional installer(s).

Secondly the DC-Air™ will not work without the calibration file which is controlled by Athlos and resides in the cloud.

There are therefore two levels of protection against unauthorized installation by a non-professional and unauthorized use.

Thank you for your attention to this matter.

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X-ray imaging technology

Yours faithfully

Company DocuSigned by:

Athlos Oy

Signature DocuSigned by:

Konstantinos Spartiotis Ph.D.

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CEO

1/19/2022

Full Name

Konstantinos Spartiotis Ph.D.

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