



Food and Drug Administration  
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June 9, 2015

AprioMed AB  
Mr. Bruno Edling  
Quality Manager  
Virdings Allé 28  
754 50 Uppsala  
SWEDEN

Re: K150625

Trade/Device Name: Morrison Steerable Needle  
Regulation Number: 21 CFR 876.1075  
Regulation Name: Gastroenterology-urology biopsy instrument  
Regulatory Class: Class II  
Product Code: KNW  
Dated: February 5, 2015  
Received: March 11, 2015

Dear Mr. Edling:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Jennifer R. Stevenson -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## 4 Indications for Use Statement

510(k) Number (if known):           K150625          

Device Name:           Morrison Steerable Needle          

The Morrison Steerable Needle is intended for percutaneous injection and aspiration procedures, and tissue sampling in kidney, liver, muscle and subcutaneous tissue.

Prescription Use       X        
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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## 5 510(k) Summary (per 21 CFR 807.92(c))

### 5.1 Submitter/510(k) Holder

AprioMed AB  
Virdings Allé 28  
Uppsala, SWEDEN 754 50

Contact Person: Bruno Edling, Quality Manager  
Telephone: +46184301445

Date Prepared: February 5, 2015

### 5.2 Device

Proprietary Name: Morrison Steerable Needle  
Common/Usual Names: Biopsy Needle  
Classification Names: Instrument Biopsy  
510(k) number: K150625  
Product Code: KNW

### 5.3 Predicate Devices

Legally marketed Biopsy Instruments used for the same indications for use:

Proprietary Name: Angiotech Chiba Biopsy Needle (Former Manan Soft Tissue Biopsy Needle)  
Common/Usual Names: Angiotech Chiba Biopsy Needle  
Classification Names: Instrument Biopsy  
510(k) number: K980122  
Product Code: KNW

Proprietary Name: Pan Chiba Cytological Aspirating Biopsy Needle  
Common/Usual Names: Pan Chiba Cytological Aspirating Biopsy Needle  
Classification Names: Instrument Biopsy  
510(k) number: K970872  
Product Code: KNW

### 5.4 Device Description

The sterile, single use, Morrison Steerable Needle consists of the housing, a rotating lever which controls the deflection of the needle tip, the slide, the collar which transfers tensile force from the slide to the core wire; the tendon wire (core wire) which transfers tensile force from the collar to distal tip of the tubing; the stainless steel tubing which ends in a Menghini like needle tip on the distal end and a luer lock fitting on the proximal end.

When the lever is rotated, the rotational force is transferred in the cam curve into tensile force on the slide which is pulled towards the proximal end of the device. The slide brings the collar and the proximal end of the core wire along and transfers the tensile force to the distal tip of the tubing, where the tensile force is transferred into bending force at the notch, causing the distal needle tip to bend towards the lever. The maximum deployment of the lever (125°) causes a 2 mm movement of collar producing a needle tip displacement of 10 mm. Since lever adjustment is seamless, any lever adjustment between 0-125° can be achieved, producing a needle tip displacement of 0-10 mm.

The materials used for construction of the Morrison Steerable Needle are typical for this type of medical device. The only material in direct patient contact is stainless steel AISI 304, commonly used in medical devices.

## **5.5 Indications for Use**

The Morrison Steerable Needle is intended for percutaneous injection and aspiration procedures, and tissue sampling in kidney, liver, muscle and subcutaneous tissue.

The Intended use for the legally marketed devices are:

For the Manan device; The Manan soft tissue Biopsy Needles are intended to be used in percutaneous soft tissue (pleura cavity associated organs, abdominal cavity and associated organs, etc.) biopsies effected via the insertion of device by a qualified physician, under guidance (CT, Ultrasound, Sequential Mammography, or Floroscopy), and manipulated in such a manner that a tissue specimen is retained within a collection orifice on the needle.

And;

For the PAN device; This device is to be used for taking cyto-histological biopsies of soft tissue

Though the indication for use descriptions are not exactly the same, the meaning is essentially the same. All devices are intended for the same procedure in soft tissue

## **5.6 Comparison of Technological Characteristics of Morrison Steerable Needle Compared to Legally Marketed Biopsy Needles Used for the Same Indications for Use**

AprioMed AB has determined that the Morrison Steerable Needle is substantially equivalent to legally marketed devices based on the Indications for Use, compliance with internationally recognized design and performance standards, materials specifications, use environments, and performance. The determination of equivalence is also based on the fact that the differences between the Morrison Steerable Needle and legally marketed rigid needles used for the same Indications for Use do not raise new issues of safety and effectiveness based on the formal risk analysis.

Information and data presented in this 510(k) shows that Morrison Steerable Needle is equivalent to the legally marketed devices and does not raise new issues of safety or effectiveness.

A side-by-side comparison of the Morrison Steerable Needle and the applicable legally marketed devices is provided in Table 5-1 below.

Table 5-1. Comparison of the Morrison Steerable Needle with Legally Marketed Devices

<b>Parameter</b>	<b>Morrison Steerable Needle</b>	<b>Angiotech Chiba 20G 15cm/ 22G 15cm</b>	<b>Pan Chiba 20G 20cm/ 22G 20cm</b>	<b>Equivalent Yes/No</b>
510(k) no.	K150625	K980122	K970872	N/A
Proprietary Name	Morrison Steerable Needle	Manan Soft Tissue Biopsy Needles	Pan Apirating Needle (Chiba)	N/A
Device Classification Name	Instrument, Biopsy	Instrument, Biopsy	Instrument, Biopsy	YES
Product Code	KNW	KNW	KNW	YES
Regulation description	Gastroenterology-urology biopsy instrument	Gastroenterology-urology biopsy instrument	Gastroenterology-urology biopsy instrument	YES
Regulation Number	21 CFR 878.1075	21 CFR 878.1075	21 CFR 878.1075	YES
Intended Use/ Indications for Use	The Morrison Steerable Needle is intended for percutaneous injection and aspiration procedures, and tissue sampling in kidney, liver, muscle and subcutaneous tissue.	The Manan soft tissue Biopsy Needles are intended to be used in percutaneous soft tissue (pleura cavity associated organs, abdominal cavity and associated organs, etc.) biopsies effected via the insertion of device by a qualified physician, under guidance (CT, Ultrasound, Sequential Mammography, or Florescopy), and manipulated in such a manner that a tissue specimen is retained within a collection orifice on the needle.	This device is to be used for taking cyto-histological biopsies of soft tissue	YES
Visualization technique	Conventional imaging guidance equipment excluding MRI	Conventional imaging guidance equipment excluding MRI	Conventional imaging guidance equipment excluding MRI	YES
Single Use	Yes	Yes	Yes	YES
Sterile	Yes	Yes	Yes	YES

Parameter	Morrison Steerable Needle	Angiotech Chiba 20G 15cm/ 22G 15cm	Pan Chiba 20G 20cm/ 22G 20cm	Equivalent Yes/No
Needle material	Medical grade Stainless Steel	Medical grade Stainless Steel	Medical grade Stainless Steel	YES
Needle Hub	Luer hub	Luer hub	Luer hub	YES
Needle size	21G 17cm	20G 15cm/22G 15 cm	20G 20cm	YES
Stylet Size	OD: 0,64 mm	OD 20G: 0.60mm/ OD 22G: 0.40mm	OD 20G: 0.60mm/ OD 22G: 0.40mm	YES
Needle advancement/penetration depth	17cm free length	15cm free length	20cm free length	YES
Sample notch size	N/A Device does not have sample notch	N/A Device does not have sample notch	N/A Device does not have sample notch	YES
Number of samples	N/A as the device is not a Biopsy Gun	N/A as the device is not a Biopsy Gun	N/A as the device is not a Biopsy Gun	YES
Safety features	N/A no specific safety features	N/A no specific safety features	N/A no specific safety features	YES
Anatomical sites	Liver, kidney, muscle and subcutaneous tissue	Pleura cavity associated organs, abdominal cavity and associated organs, etc	Soft tissue	YES
Steerable	Yes	No	No	YES

A summary of the basis for the determination of substantial equivalence is described below.

### 5.6.1 Intended Use/Indication for Use

AprioMed has determined that the Morrison Steerable Needle is substantially equivalent to the legally marketed devices based on intended use/indications for use. Though the indication for use descriptions are not exactly the same, the meaning is essentially the same. All devices are intended for the same procedure in soft tissue

### 5.6.2 Materials

AprioMed has determined that the Morrison Steerable Needle is substantially equivalent to legally marketed devices based on materials. Both the Morrison Steerable Needle and legally marketed devices are constructed with medical grade stainless steel.

### 5.6.3 Use Environment

AprioMed has determined that the Morrison Steerable Needle is substantially equivalent to legally marketed devices based on the use environment. Both the Morrison Steerable Needle and legally marketed needles/devices are used under conventional imaging guidance equipment excluding MRI. The users are physicians trained in image guided injection/aspiration procedures and tissue sampling.

#### **5.6.4 Fundamental Design**

##### **Size, stylet size and penetration depth**

AprioMed has determined that the Morrison Steerable Needle size, stylet size and penetration depth is substantially equivalent to legally marketed devices.

##### **Sample notch size**

AprioMed believes that the Morrison Steerable Needle is substantially equivalent to legally marketed devices with respect to sample notch size. Sample notch is not present in the design of the Morrison Steerable needle or any of the state of the art predicate devices. Sample notch is present on gastroenterological biopsy guns but not on biopsy needles.

##### **Number of samples**

AprioMed believes that the Morrison Steerable Needle is substantially equivalent to legally marketed devices with respect to number of samples. Neither the Morrison Steerable needle nor the predicates specifies number of samples. To specify number of samples is a requirement for Biopsy guns as there is a known risk of mechanical failure when using this type of devices, and there is no such risk for biopsy needles.

##### **Safety features**

AprioMed believes that the Morrison Steerable Needle is substantially equivalent to legally marketed devices with respect to safety features. Neither the Morrison Steerable needle nor the predicates has any specific safety features.

### **5.7 Performance Data**

#### **5.7.1 Biocompatibility testing**

The Morrison Steerable Needle has successfully been tested for:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity

The testing results verify that the biocompatibility criteria given in ISO 10993 are fulfilled.

Based on the test reports, AprioMed concludes that the Morrison Steerable Needle is non-toxic and biocompatible.

#### **5.7.2 Performance testing bench**

##### **Needle advancement**

AprioMed believes that the Morrison Steerable Needle is substantially equivalent to legally marketed devices with respect to needle advancement. The Morrison Steerable Needle can access the targeted tissue and give an accurate needle advancement and penetration when compared with similar predicate devices advanced in intended anatomical sites, the control

article and test articles were equivalent in terms of needle advancement accuracy and penetration force.

### **Injection/Aspiration**

AprioMed believes that the Morrison Steerable Needle is substantially equivalent to legally marketed devices with respect to Injection/ Aspiration. The procedures for Injection and Aspiration, are identical for all needles.

### **Tissue sampling**

AprioMed believes that the Morrison Steerable Needle is substantially equivalent to legally marketed devices with respect to demonstrating that the Morrison Steerable Needle is able to collect an appropriate amount of tissue for biopsy, as compared to the predicate devices in the anatomical sites; muscle, kidney, liver and subcutaneous tissue.

Tissue sampling for the Morrison Needle and the predicates demonstrates that the device is able to collect at least as much tissue for biopsy, as compared to the predicate devices in the anatomical sites; muscle, kidney, liver and subcutaneous tissue.

(See APPENDICE 18-4 R1489 Performance testing bench Morrison Steerable Needle)

### **5.7.3 Performance testing Animal**

To further test the safety of using the Morrison Steerable Needle an in vivo Animal Safety study has been performed (see Section 19 and associated APPENDICES). The evaluation and testing is summarized below.

The study successfully achieved the objective of demonstrating that the Morrison steerable needle is significantly comparable in safety to the 20 and 22 Gauge Pan Chiba and 20 and 22 Gauge Angiotech Chiba biopsy needles.

## **5.8 Summary and Conclusions**

Based on the above discussion, AprioMed has determined that Morrison Steerable Needle is equivalent to the predicates. AprioMed has demonstrated the safety of using the Morrison Steerable Needle, when compared to the prediactes, under the indication percutaneous injection and aspiration procedures, and tissue sampling in kidney, liver, muscle and subcutaneous tissue.