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1 2 >

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Trade Name	Applicant	PMA Number	Decision Date
<a href="#">ACHILLES EXPRESS ULT</a>	Ge Lunar Corp.	P970040 S003	07/30/2004
<a href="#">OSTEOSPACE</a>	Medilink	P010058	03/15/2004
<a href="#">OMNISENSE 7000S ULTR</a>	Sunlight Medical Ltd	P990035 S005	11/17/2003
<a href="#">SUNLIGHT OMNISENSE B</a>	Sunlight Medical Ltd	P990035 S006	04/24/2003
<a href="#">SUNLIGHT OMNISENSE 7</a>	Sunlight Medical Ltd	P990035 S003	05/24/2002
<a href="#">MCCUE CUBA CLINICAL</a>	Coopersurgical, Inc.	P990016 S002	03/28/2002
<a href="#">SUNLIGHT OMNISENSE 7</a>	Sunlight Medical Ltd	P990035 S004	11/30/2001
<a href="#">MC CUE PLC CUBA CLIN</a>	Mccue Plc	P990016 S001	11/08/2001
<a href="#">ACHILLES INSIGHT ULT</a>	Ge Lunar Corp.	P970040 S002	10/24/2001
<a href="#">SUNLIGHT OMNISENSE U</a>	Sunlight Medical Ltd	P990035 S002	07/27/2001

Database Updated 8/08/2005

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510 | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)  
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[CFR Title](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)  
 21

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Trade Name	Applicant	PMA Number	Decision Date
<a href="#">UBIS 5000 BONE SONOM</a>	Diagnostic Medical S	P000055	07/17/2001
<a href="#">OMNISENSE 7000S ULTR</a>	Sunlight Medical Ltd	P990035 S001	06/21/2001
<a href="#">DTU-ONE ULTRASOUND S</a>	Osteometer Meditech,	P980010	09/19/2000
<a href="#">THE SUNLIGHT OMNISEN</a>	Sunlight Ultrasound	P990035	01/20/2000
<a href="#">MCCUE CUBACLINICAL U</a>	Coopersurgical, Inc.	P990016	01/07/2000
<a href="#">HOLOGIC SAHARA CLINI</a>	Hologic, Inc.	P970017 S001	04/29/1999
<a href="#">ACHILLES EXPRESS ULT</a>	Lunar	P970040 S001	04/23/1999
<a href="#">ACHILLES EXPRESS ULT</a>	Ge Lunar Corp.	P970040	06/26/1998
<a href="#">MYRIAD ULTRASOUND SY</a>	Myriad Ultrasound Sy	P970026	05/29/1998
<a href="#">SAHARA CLINICAL BONE</a>	Hologic, Inc.	P970017	03/12/1998

Database Updated 8/08/2005

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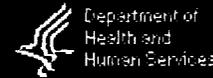
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Note: this medical device has supplements. The device description may have changed. Be sure to look at the supplements to get an up-to-date view of this device.

**Premarket Approval (PMA) Database**

<b>Trade Name</b>	ACHILLES EXPRESS ULTRASONOMETER
<b>Classification Name</b>	<a href="#">Bone Sonometer</a>
<b>Generic Name</b>	Ultrasonometer
<b>Applicant</b>	<a href="#">GE LUNAR CORP.</a>
<b>PMA Number</b>	P970040
<b>Date Received</b>	09/02/1997
<b>Decision Date</b>	06/26/1998
<b>Product Code</b>	MUA
<b>Docket Number</b>	98M-0715
<b>Notice Date</b>	10/07/1998
<b>Advisory Committee</b>	Radiology
<b>Expedited Review Granted?</b>	No

**Approval Order Statement** The device is indicated as follows: the achilles+ultrasonometer measures ultrasound variables of the os calcis to provide a clinical measure called stiffness index. The stiffness index indicates risk of osteoporotic fracture in postmenopausal women comparable to bone mineral density (bmd) as measured by x-ray absorptiometry at the spine or hip. Stiffness index results expressed as t-scores are used to assist the physicians in the diagnosis of osteoporosis in the same way as are t-scores or obtained by x-ray absorptiometry. Either the stiffness index t-score or x-ray absorptiometry t-score can be utilized by a physician, in conjunction with other clinical risk factors, to provide a comprehensive skeletal assessment. The stiffness index has a precision error in older women comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes.



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<b>Trade Name</b>	OSTEOSPACE
<b>Classification Name</b>	<a href="#">Bone Sonometer</a>
<b>Generic Name</b>	Ultrasound Bone Sonometer
<b>Applicant</b>	<a href="#">MEDILINK</a>
<b>PMA Number</b>	P010058
<b>Date Received</b>	10/03/2001
<b>Decision Date</b>	03/15/2004
<b>Product Code</b>	MUA
<b>Docket Number</b>	05M-0024
<b>Notice Date</b>	01/21/2005
<b>Advisory Committee</b>	Radiology
<b>Expedited Review Granted?</b>	No

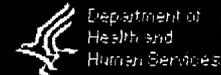
**Information About:** [Labeling, Approval Order, Summary Of Safety And Effectiveness](#)

**Approval Order Statement** Approval for the osteospace. The osteospace is a quantitative ultrasound bone sonometer device (qus) to be used for the measurement of broadband ultrasound attenuation (bua) of the calcaneus, as an aid, together with other clinical risk factors, to diagnose osteoporosis and other medical conditions leading to reduced bone strength and to estimate the risk of subsequent atraumatic fracture. The output is expressed in terms of bua, t-score, and z-score.

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Note: this medical device has supplements. The device description may have changed. Be sure to look at the supplements to get an up-to-date view of this device.

**Premarket Approval (PMA) Database**

<b>Trade Name</b>	THE SUNLIGHT OMNISENSE(TM) ULTRASOUND BONE SONOMETER
<b>Classification Name</b>	<a href="#">Bone Sonometer</a>
<b>Generic Name</b>	Ultrasound Bone Sonometer
<b>Applicant</b>	<a href="#">SUNLIGHT ULTRASOUND TECHNOLOGIES LTD.</a>
<b>PMA Number</b>	P990035
<b>Date Received</b>	06/30/1999
<b>Decision Date</b>	01/20/2000
<b>Product Code</b>	MUA
<b>Docket Number</b>	00M-0577
<b>Notice Date</b>	02/16/2000
<b>Advisory Committee</b>	Radiology
<b>Expedited Review Granted?</b>	No
<b>Information About:</b>	<a href="#">Labeling, Approval Order, Summary Of Safety And Effectiveness</a>

**Approval Order Statement** The sunlight omnisense ultrasound bone sonometer is a non-invasive device that is designed for the quantitative measurement of the velocity of ultrasound waves ("speed of sound" or "sos in m/sec") propagating along the distal one-third of the radius bone. Sos provides a measure of skeletal fragility. The output is also expressed as a t-score and z-score and can be used in conjunction with other clinical risk factors as an aid to the physician in diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and, ultimately, in the determination of fracture risk. The sos measured by omnisense

has a precision error low enough in comparison with the expected annual change in a pateints' measurement to make it suitable for monitoring bone changes which occur in the early years following menopause (i. E. , age range approximately 50-65 years). X.

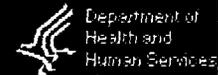
**Supplements:**                    [S001](#) [S002](#) [S003](#) [S004](#) [S005](#) [S006](#)

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[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)[New Search](#)[Back To Search Results](#)

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**Premarket Approval (PMA) Database**

<b>Trade Name</b>	MCCUE CUBACLINICAL ULTRASONIC BONE SONOMETRY SYSTEM WITH CUBAPLUS+ V4.1.0
<b>Classification Name</b>	<a href="#">Bone Sonometer</a>
<b>Generic Name</b>	Ultrasonic Bone Densitometer
<b>Applicant</b>	<a href="#">COOPERSURGICAL, INC.</a>
<b>PMA Number</b>	P990016
<b>Date Received</b>	03/08/1999
<b>Decision Date</b>	01/07/2000
<b>Product Code</b>	MUA
<b>Docket Number</b>	00M-0580
<b>Notice Date</b>	02/15/2000
<b>Advisory Committee</b>	Radiology
<b>Expedited Review Granted?</b>	No
<b>Information About:</b>	<a href="#">Labeling, Approval Order, Summary Of Safety And Effectiveness</a>
<b>Approval Order Statement</b>	Approval to perform a quantitative ultrasound measurement of the calcaneus (heel bone), the results of which can be used in conjunction with other clinical risk factors as an aid for the diagnosis of osteoporosis and other medical conditions leading to reduced bone density and, ultimately, for the determination of fracture risk.
<b>Supplements:</b>	<a href="#">S001</a> <a href="#">S002</a>

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## CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [CDRH A-Z Index](#) | [Contact CDRH](#)[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)  
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<b>Trade Name</b>	UBIS 5000 BONE SONOMETER
<b>Classification Name</b>	<a href="#">Bone Sonometer</a>
<b>Generic Name</b>	Bone Sonometer
<b>Applicant</b>	<a href="#">DIAGNOSTIC MEDICAL SYSTEMS</a>
<b>PMA Number</b>	P000055
<b>Date Received</b>	12/18/2000
<b>Decision Date</b>	07/17/2001
<b>Product Code</b>	MUA
<b>Docket Number</b>	01M-0360
<b>Notice Date</b>	08/23/2001
<b>Advisory Committee</b>	Radiology
<b>Expedited Review Granted?</b>	No
<b>Information About:</b>	<a href="#">Labeling, Approval Order, Summary Of Safety And Effectiveness</a>

**Approval Order Statement** Approval for the ubis 5000. The ubis 5000 is a quantitative ultrasound (aus) bone sonometer and is indicated for the measurement of broadband ultrasound attenuation (bua) of the calcaneus, as an aid to diagnose osteoporosis and to estimate the risk of subsequent atraumatic fracture. The output is expressed in terms of both bua and t-score.

Database Updated 6/06/2

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[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [CDRH A-Z Index](#) | [Contact CDRH](#)[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)  
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)[New Search](#)[Back To Search Results](#)**Premarket Approval (PMA) Database**

<b>Trade Name</b>	DTU-ONE ULTRASOUND SCANNER
<b>Classification Name</b>	<a href="#">Bone Sonometer</a>
<b>Generic Name</b>	Bone Sonometer
<b>Applicant</b>	<a href="#">OSTEOMETER MEDITECH, INC.</a>
<b>PMA Number</b>	P980010
<b>Date Received</b>	04/15/1998
<b>Decision Date</b>	09/19/2000
<b>Product Code</b>	MUA
<b>Docket Number</b>	00M-1615
<b>Notice Date</b>	11/15/2000
<b>Advisory Committee</b>	Radiology
<b>Expedited Review Granted?</b>	No
<b>Information About:</b>	<a href="#">Labeling, Approval Order, Summary Of Safety And Effectiveness</a>

**Approval Order Statement** Approval for the dtu-one ultrasound scanner. The dtu-one is intended to perform quantitative ultrasound measurement of the calcaneus (the heel bone), the results of which can be used in conjunction with other clinical risk factors as an aid to the physician in diagnosis of osteoporosis (t-score) and in the determination of fracture risk in men and women. The measurement may also be used in caucasian women to aid in the detection of medical conditions, other than age-related bone loss, that lead to reduced bone density.

Database Updated 6/06/20



## CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [CDRH A-Z Index](#) | [Contact CDRH](#)[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)  
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<b>Trade Name</b>	MYRIAD ULTRASOUND SYSTEMS LTD. SOUNDSCAN
<b>Classification Name</b>	<u>Bone Sonometer</u>
<b>Generic Name</b>	Quantitative Ultrasound (Qus) For Bone Assessment
<b>Applicant</b>	<u>MYRIAD ULTRASOUND SYSTEMS LTD.</u>
<b>PMA Number</b>	P970026
<b>Date Received</b>	07/01/1997
<b>Decision Date</b>	05/29/1998
<b>Product Code</b>	MUA
<b>Docket Number</b>	98M-0722
<b>Notice Date</b>	09/09/1998
<b>Advisory Committee</b>	Radiology
<b>Expedited Review Granted?</b>	No

**Approval Order Statement** Perform quantitative ultrasound measurement of tibia (shin bone), the results of which can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and medical conditions leading to reduced bone strength and ultimately, in the determination of fracture risk. The soundscan measures the velocity of ultrasound (speed of sound, sos, in m/sec) along the tibia, exclusively within bone, unaffected by overlying soft tissue. Sos along the tibia provides an index of bone strength, with stronger bone having higher velocities. As such the soundscan provides a measure of skeletal fragility. The soundscan reports sos along with both t- and z-scores.

Database Updated 6/06/20



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FDA Home Page | CDRH Home Page | Search | CDRH A-Z Index | Contact CDRH



510(k) | Registration | Listing | Adverse Events | PMA | Classification | CLIA
CFR Title 21 | Advisory Committees | Assembler | NHRIC | Guidance | Standards

New Search

Back To Search Results

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Premarket Approval (PMA) Database

Table with 2 columns: Field Name and Value. Fields include Trade Name (SAHARA CLINICAL BONE SONOMETER), Classification Name (Bone Sonometer), Generic Name (Acoustic Bone Densitometer), Applicant (HOLOGIC, INC.), PMA Number (P970017), Date Received (04/07/1997), Decision Date (03/12/1998), Product Code (MUA), Docket Number (98M-0187), Notice Date (04/16/1998), Advisory Committee (Radiology), Expedited Review Granted? (No).

Approval Order Statement Approval for the sahara clinical bone sonometer. The intended use of the sahara clinical bone sonometer is to: perform a quantitative ultrasound measurement of the calcaneus (heel bone), the results of which can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the determination of fracture risk. Sahara measures the speed of sound (sos, in m/s) and broadband ultrasonic attenuation (bua, in db/mhz) of an ultrasound beam passed throught he calcaneus, and combines these results linearly to obtain the quantitative ultrasound index (qui). The output is also expressed as a t-score and as an estimate of the bone mineral density (bmd, in g/cm2) of the calcaneus as measured by dual energy x-ray absorpiometry (dxa).

Supplements: S001